

# **HIT Policy Committee Meeting Final Transcript July 21, 2010**

## **Presentation**

### **Judy Sparrow – Office of the National Coordinator – Executive Director**

Thank you. Good morning, everybody, and welcome to the 14<sup>th</sup> meeting of the HIT Policy Committee. This is a federal advisory committee, so there will be opportunity at the close of the meeting for the public to make comments. Also, the full transcript of the meeting will be on the ONC Web site. Just a reminder to workgroup members to please identify yourselves when speaking for attribution, and let's go around the table now and introduce ourselves briefly, beginning on my left with Michael Weiner.

### **Michael Weiner – Defense Health Information Management System – CMO**

Michael Weiner, Department of Defense, Military Health.

### **Deven McGraw - Center for Democracy & Technology – Director**

Deven McGraw, Center for Democracy & Technology.

### **Charles Kennedy – WellPoint – VP for Health IT**

Charles Kennedy, WellPoint.

### **Gayle Harrell – Florida – Former State Legislator**

Gayle Harrell, former state representative from Florida.

### **Scott White – 1199 SEIU – Assistant Director & Technology Project Director**

Scott White, 1199 SEIU.

### **David Blumenthal – Department of HHS – National Coordinator for Health IT**

David Blumenthal, ONC.

### **Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Paul Tang, Palo Alto Medical Foundation.

### **Paul Egerman – eScription – CEO**

Paul Egerman, software entrepreneur.

### **Christine Bechtel - National Partnership for Women & Families – VP**

Christine Bechtel, National Partnership for Women & Families.

### **Rick Chapman – Kindred Healthcare – Chief Administrative Officer/CIO/EVP**

Rick Chapman, Kindred Healthcare.

### **Neil Calman - Institute for Family Health - President & Cofounder**

Neil Calman, Institute for Family Health.

### **Judy Faulkner – Epic Systems – Founder**

Judy Faulkner, Epic.

**Marc Probst – Intermountain Healthcare – CIO**

Marc Probst, Intermountain Healthcare.

**Adam Clark – Lance Armstrong Foundation – Director for Health Policy**

Adam Clark, Livestrong.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Let me ask are there any committee members on the telephone? All right. With that, I'll turn it over to Dr. Blumenthal.

**Art Davidson - Public Health Informatics at Denver Public Health – Director**

Judy, this is Art Davidson.

**David Blumenthal – Department of HHS – National Coordinator for Health IT**

Welcome, again. I can't help but this meeting reflecting back on our first meeting, probably 14 months ago, maybe 13. But not nearly long enough to predict the amount of work that has been accomplished here. I hope that you all saw in the meaningful use rule, the level of influence that you've had on the thinking of the department and the administration on meaningful use. The choice framework that you propose for us heavily influenced what we did. Many of your recommendations were accepted, and as I've said before, it shows the extent to which your careful thinking and advice has made it possible for us to accomplish what we've accomplished up to this point.

You'll hear more from Tony Trenkle and Farzad Mostashari about the content of the rule, if you haven't had a chance to read all or many hundreds of pages. It will remain there for you to digest at your pleasure and leisure. But the framework is heavily reflective of your advice, and I think the launch and the announcement went well. There's obviously going to be conflicting opinions about whether we achieved exactly the right balance between pushing the industry to a new level of performance and making it achievable. We described the new rule as ambitious, but achievable. I hope it actually attains that set of balanced objectives.

We've, of course, also announced a standards certification rule, which has not surprised me, attracted much less attention, but it's also extremely important. That one also changed considerably in response to comments that we received from our standards committee and became much more specific on the requirements for interoperability, which was generally the recommendation that we got in comments, and also the recommendation we got from our standards committee in their formal comments on the rule.

In any case, we're launched. We have now our major rules. We have all our major grant programs. We are working hard on the NHIN Direct and the NHIN Exchange, and so we are now in the kind of implementation mode. And, strange as it may seem, though we have just started work on the actual implementation of the first stage of meaningful use, we are already beginning to think about the next stage of meaningful use.

I want to assure everyone around the table, especially those who are sensitive to the realities of working in the real world that we are not about to change the rules within nanoseconds of having released the first set of rules. But there was unfinished business. There were things that we teed up the first time around that we just didn't have a chance to think carefully about, and so now we have a period of time, perhaps to reflect on the long-range goals, the major new directions, unfinished business that we couldn't spend enough time to think about in the first stage of meaningful use.

Just for the record, we're not changing anything at this point. We're not rewriting meaningful use. What I think we're going to be doing over the next several months is thinking about broad directions, future directions, where we want to be going, what the gaps are, and how we can begin to, and what we've learned from the first go round and where we want to be in a couple of years from now.

I should also just let you know that the temporary certification process, the rule on that, of course, came out mid June. We began accepting applications July 1<sup>st</sup>. We've had close to 30 applications. I'm sorry. We've sent out close to 30 applications. We've received, I think, six or seven now completed applications, and so we're optimistic that we will have a new landscape in the certification realm that instead of having a single certification body, there will be more opportunity, a broader pipeline towards certification, hopefully more price competition and shorter waiting times to get to certification, and an opportunity for us to see a little bit of variation in the process of certification and, therefore, some understanding of which types of processes work best. That change in the landscape seems to be off to a good start.

In the fall, we will be probably releasing the final rule on the permit certification process, which will probably take about a year to get up and running to replace the temporary certification process. So no rest for the weary, but perhaps a little bit less of a sprint. We're now into a period where we can, I think, reflect a little bit more on some things. You will, of course, be hearing more about privacy and security issues later on today. That's not an area where we have a lot of opportunity to rest because all our grantees, many of the folks who are looking to the federal government for leadership are anxious to know what we think about the big issues that they're confronting. Our state grantees, our regional extension centers are hopeful that we can't necessarily tell them what to do. We can at least advise them about what to do. So that's an area where we're still working full speed ahead.

With those sort of introductory comments, I'll turn it over to Paul. I apologize. I have to fly to the Midwest at about 11:30, so I'm going to be leaving a little bit early. Now that we have all this stuff to talk about, I've got my bag packed, and the federal travel agent is busy sending me around the country to tell people what you all have been doing and what we've been doing.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Thank you very much, David. I want to certainly begin by congratulating you personally and the office and CMS for a tremendous set of accomplishments over the past, just a little over a year. The pace has been astounding. We all know that. But it's the pace and the comprehension of all the programs that have been administered just in this past year that I think is going to set the country on – has already set the country in a dramatic step forward and towards the goals, the reform and the outcomes goals that we all sought, so really truly thank you very much.

I think you really did achieve a workable balance, as you said, between where we need to go and the achievements we need to strive for, and recognizing where we're starting from, but we still have a time pressure that's not just the rule. It's really the country's need for this information. Thanks very much, and I want to thank you.

We will begin right after my few minutes to the meat in terms of the moment we've all been waiting for, which is to hear from CMS, from Tony Trenkle about the meaningful use rule that was just released last year, not even officially published in the federal register. Go on and talk about other, the still important ongoing activities in ONC in the various programs that it administers, get a briefing on the enrollment update, the enrollment project that we heard about briefly from Aneesh last month, and continue on to this tiger team, which is tackling the challenging aspects of privacy, but we still have to get them nailed to

some extent so that the entire country can move forward on this. It's always been there. The time has come.

Then move on to hear about what the adoption certification workgroup is going to be doing in the immediate future and an update from the information exchange workgroup, so a full agenda in terms of reports, still a lot of work to be done, and we're going to find out what's going on in these various activities. We'll begin with Tony Trenkle and updating us on the meaningful use rule, and I don't know if Farzad is here. Thank you.

**Tony Trenkle – CMS – Director of OESS**

Good morning, everyone. I just figured the journey to meaningful use, as David said, it reminded me of a saying, —“ith is the bird that sings when the dawn is still dark,” and I think all of you were doing a lot of singing about a year ago when we didn't know what the framework of this was going to be. I join David in congratulating all of you, as well as my colleagues at CMS and ONC and other places for the work that was done, the input that was given, and the final result that may not have pleased everyone, but I think it represents a major step forward, and it really puts some meat on the bones that Congress gave us 17 months ago or, rather 15. Well, 17 months ago. It seems like 17 years ago, but anyhow.

What I'm going to try to do today, I'm sure you've all read the 900-page rule, so this won't be new to you, but those of you who may not have read all of it, I will try to just summarize some of the areas and some of the changes we've made between the NPRM and the final, recognizing the contributions that the policy committee made, both before the NPRM and also the recommendations you've made after the NPRM came out. Just to go over a little history, of course, we've passed, the law was passed the 17<sup>th</sup> of February. We began hearings with the NCVHS in late April. Last summer and fall, the policy committee spent a lot of time.

I don't know if any of you pulled out the first matrix. I went back and just pulled it out and took a look at it last week when I was just starting to get some slides ready for today. It's quite interesting. I mean, some of the framework, of course, has stayed the same, but there has been quite a bit of involvement over the last year, and it's kind of interesting when you see how far we've gone and the changes we've made. It's quite amazing since last June was when we had the first matrix unveiled and sent out for public comment.

After the rule went out in January, of course, we got over 2,000 comments, as you all heard. I don't have the exact number, but the difference between this and a lot of CMS rules, we get a lot more comments on this one on a lot of our rules. We do payment rules every year, but the substance of the comments and the complexity of this compared a lot of the efforts that we do, and we put out a lot of regs, but this is one of the few that covers the Medicare fee for service, Medicare advantage, and the Medicaid programs, as well as require a lot of coordination with ONC along the way is somewhat unique. We had a guy who was very much engaged in the Medicare fee for service world, and he retired a few weeks ago after having provided a lot of work on this regulation. He said it was the first time in his 30+ year career that he'd ever worked this extensively with the Medicaid side, and he said he learned stuff about the Medicaid program he never knew, so that was quite fascinating that someone could be such a policy expert at CMS for so long and because of the divergence of the programs, had never really come together in such a way. I think that's a critical achievement as well.

What didn't change and what did change? We, of course, stayed close to the statute as much as possible. The goals that we set originally and the policy committee recommended back last year stayed the same. We had a lot of comments on the hospital definition. There was a lot of concern that came out. Some of you who may have heard the ... and means hearing yesterday heard some of the concerns

of some of the congressmen on the multi-campus issue and some of the push by some of the hospitals. Here he is, Farzad, with a regular tie, so this must be a critical moment, Farzad.

**Farzad Mostashari – NYC DH&MHH – Assistant Commissioner**

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**Tony Trenkle – CMS – Director of OESS**

I've been working with Farzad for almost a year now, and this is only the second time I've seen you in a regular tie, Farzad.

Anyhow, back to the hospital definition, there is some push within Congress to change that because of the policies that we have with defining hospitals and the way hospitals have chosen to define themselves for other payment purposes. We remain consistent in the final rule.

Another issue that came up was whether EPs would be required to demonstrate individually or whether they could come in through groups, and at least for this regulation, we decided we would maintain the demonstration individually and reporting individually. The clinical quality measures timeline will remain the same. We got some pushback on that in terms of reporting measures electronically in 2012, but we are remaining that the same. And the meaningful use reporting period will be 90 days for the first year and one year thereafter. Of course, all these things, as David mentioned in terms of unfinished business, a number of these will certainly be issues that get raised either within this committee or by others, as we move towards stage two rulemaking, which will be happening this time next year.

A lot of things did change, and we'll get into some of these meaningful use criteria and the quality measures. The hospital based EP was changed by legislation, the Medicaid acute hospitals, patient volume, and a couple other changes in Medicaid. And then we also decided to synchronize all programs to start registration in 2011.

I mentioned the provider eligibility. That was a major change that Congress decided to make. If you recall, there was, in the original legislation, it was hospital based EPs included those who were in an outpatient setting, but had substantial reporting of billing in a hospital setting, even if they were outpatient, and Congress changed that, so now it is defined as inpatient or ER setting. Of course, that makes a larger number of hospital based eligible professionals now eligible for the EP incentive payments.

The other change was Medicaid included critical access hospitals in its definition of acute care, so now that this will change so that critical access hospitals can also be eligible for Medicaid payments, as well as Medicare payments. Just a couple of changes in the Medicaid patient volume, there was some concern about the high bar for Medicaid patient volume, so we did actually expand that to enable more providers to be eligible under the Medicaid side.

Let's talk a little bit about meaningful use. We kept the same priorities, as I mentioned. And this is a summary of the changes from the original rule, many of which reflect the recommendations of the policy committee. In the NPRM, of course, we said you had to meet all reporting objectives. Now we have divided into the final, into a core, and into a menu set. We maintained a similar number of measures for both hospitals and for EPs. However, now EPs have to meet 20 out of 25, and hospitals 19 out of 24.

We also changed some of the thresholds, and we can talk a little bit about why we change some of those in a few moments. We received a lot of comments about the denominator to calculate the threshold. Some of them require manual review, and at this point, all of the measures that we put in with denominators do not require manual review. The administration transactions, this was an area that got a

lot of feedback from people, and we have removed that for this rule. However, we have signaled our intent to look at including it in the next stage of meaningful use objectives. Then, finally, two recommendations from the policy committee to add in patient specific education resources. Actually, it says measures ... has to be objectives for, and advanced directives were also added back in, advanced directives for hospitals, for patients 65 or older.

We received a lot of pushback on the requirement for state flexibility. We received a lot of support for state flexibility from the states, so what we've decided to do is give them some flexibility, but limit it to requiring for public health related objectives, which we now have in menu for them to come into us and ask that any of them be required as core rather than menu. The clinical quality measures, we made some major changes in that. We have a smaller number of measures, and we also removed the specialty group measures. You still must report on a total of six, but not by specialists. The hospital is required to report on 15.

Now there was some pushback in terms of whether if it was not a measure that you had a denominator for, would that be an issue. As we said, you're supposed to report on six, so even if it doesn't have a denominator, that can be one of the six that you report on at least for this particular regulation. Then the CHIPRA, the Medicaid area, we have some of the CQMs overlap with CHIPRA CORE. That was one of the areas that we wanted to make sure we had some harmonization, along with the other CMS, PQRI, and RAC DIPU or hospital reporting program.

How were the objectives chosen for CORE? We used several criteria, worked closely with ONC and with others on that. Of course, there were several in statute, e-prescribing, reporting quality measures, and demonstrating health information exchange. There were others that we felt were foundational, privacy and security, and those that provide data ... for other measures such as demographics, medication lists, problem lists, patient centered, and then part of what we consider the normal practice that the provider does and records manually should be considered part of the core objectives. And, of course, we received a lot of feedback. We also looked at how the objectives were aligned to try to make sure that we align them properly and into the core and the menu items. Also in the menu items, one of the criteria was if the infrastructure was out of the individual's provider's control, for example with lab results, we determined that was probably more appropriate, at least for this round, to put it into menu as opposed to core.

Applicability, we said where some measures were not applicable, they would be allowed to defer in the menu set. They could defer up to five. In the core set, if there is one without a denominator, they are allowed to defer it for this particular stage one.

We talked about the denominators, the fact that all of them are being able to be done electronically, and we divide it into two areas. One is the patients, all patients seen, and the other is actions or subsets of patients, so smoking cessation, things of that sort, advanced directives, other areas where – advanced directives, I believe, is just a yes or a no. I'd have to go look at that, but there are a number of these where we divided it by age and the action would be the subset or something like e-prescribing where it's one that's limited to the prescriptions actually done. We made it a subset of that.

The thresholds, we had a lot of back and forth in that. We defined a number of them in the NPRM as 80%. We kept several of them as 80% because we consider them part of standard practice, for example, maintaining active medication lists. Others we define on a case-by-case basis. One that received some interest from Congress yesterday was lowering the e-prescribing to 40%, and the reason we did that, we wanted to keep it as a core menu item, a core objective rather, because of the fact it was one of the three areas listed in the statute. We recognize that there are, in fact, some cases, there's nonparticipation by pharmacies, and there's also an issue of patient preference. Patients may prefer to send their – take their

prescription to a pharmacy that may not be connected for e-prescribing. So we decided, rather than move it out of the core set, we would limit, lower the threshold to 40%.

These are just for your reference. I know it's in the reg, but these are just some of the different objectives laid out by core set and by menu set. I'm sure most of you are familiar with these. So I want to do future stages. As we've mentioned before, we intent to propose two additional stages through future rulemaking. Future stages will be expand upon the state one criteria, and we laid out some of the framework for that in this particular regulation.

Number one, we said that the stage one menu set, we would like to transition the core set for stage two. We also want to add in the administrative transactions, raise the measurement for CPOE to 60%, and then reevaluate other measures, possibly looking at higher thresholds. Obviously this is intent. Some of this will be framed by the feedback we get on the program over the next number of months, and recommendations that come in from the policy committee.

Stage three, we decided not to add much definition to it. There are a couple of reasons for that. One is to get more feedback. Secondly is stage three falls into an area where there's major changes between the Medicare and Medicaid program. The Medicaid program moves from adopt, implement, and upgrade into a straight meaningful use stream after the first year. Medicaid also has no penalties, and penalties can be made until 2021, whereas in the Medicare program, payments stop in 2016, and a penalty or a payment adjustment occurs on 2015, so we felt those were some critical changes that would allow us to think of how we wanted to redefine the third stage, and we'll be discussing that more in the next rulemaking, but we'll certainly be defining it more in the rulemaking following that.

State flexibility, we mentioned that earlier about the four objectives. Multiple sites for EPs, we defined that as if they work in multiple locations but do not have certified EHR technology. They have to have 50% of their encounters at locations where EHR technology is available, and we base the meaningful use measures only on encounters that occur at locations where the technology is available.

This was the change to the Medicaid area where we said that they would be deemed as meaningful users for Medicaid for the hospitals. It applies to the subsection D and acute care hospitals. Clinical quality measures, I mentioned that a few moments ago. The change with the quality measures, we have now that the EPs have to report on three required core or up to three other core, as we've laid out in the regulations. They also must select 3 from an additional set of 38, and all these have electronic specifications, which was one of the concerns that people, commenters brought up when they came back from the rulemaking.

Some for 2011 and 2012, they must report on six measures, attest to them in 2011, report them electronically through the EHR in 2012. This is the core set, and then this is the alternate core set for the EPs. These are the additional measures, and then these are the measures for the hospitals and the eligible hospitals and critical access hospitals.

We also received a lot of questions about participate in other Medicare incentives programs, so we laid this out in the regulation. But, as you can see, there are several other connection points where we had existing programs, and there are certainly areas where they are eligible for other programs. The most popular one is the e-prescribing program that came out of the legislation several years ago. In that case, it was specifically defined within the regulation that if they choose to participate in the Medicare EHR incentive program, they cannot participate in the Medicare e-prescribing program. However, you can participate in the Medicaid EHR incentive program and e-prescribing program. Although the bar for Medicaid, given that we're not seeing too many people who would be able to qualify for both.

The timeline, as David said, we've now moved to another stage, and a lot of this stage will be outreach and operations. We have an extensive outreach program that we've worked very closely with ONC, their regional extension centers, the CMS regional offices. We've closely coordinated our efforts together to get out to the communities. We have a major operational activity going on within CMS. We've formed a governance board with an operations board that is looking very closely over the various systems and other requirements that need to be met over the next number of months to make sure this program goes up in time. We're working very closely with the states to make sure the linkages are done there, so although the reg work is finished, we have a lot of other work that we're busy spending our days and nights on.

The incentive payments, it says, will be made 11 months after the rule is published. And, actually, we expect that if we make payments or allow attestation in April with registration in January, that'll be the first 90 days. Then incentive payments will be made the month following that. The Medicaid providers, states, of course, can decide whether or not to participate in the program, and they can launch their programs in January of 2011 and thereafter. We expect most states, I'm not sure of the exact number, but most should be available in January or shortly thereafter.

The other dates on there are the last day for them to register and attest for 2011 is November 20, 2011. That's a slight overlap because they'll be able to register for the next payment year before that. Then February 2012 is the last day for EPs to register and attest. And I'd mentioned these other areas as well that are in statute.

We have a Web site set up where you can get information on the programs. It contains a lot of information, frequently asked questions, the press releases that both CMS and ONC have come out. ONC, of course, had a lot of information out on their Web site as well, and will continue to add and make more information available, both through the Web and through other means over the coming months.

Do I turn this over to Farzad now, Judy, or for questions? We just open it up. Okay. Well, why don't we open it up for questions?

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Christine?

**Christine Bechtel - National Partnership for Women & Families – VP**

First of all, thank you, guys, and congratulations for the publication of the final rule. This is a huge amount of work, I know, and I think the process that you used for accepting public input, both before and after the publication of the NPRM was really terrific, so thank you. My question is, and I don't know which of you would answer, but I suspect is probably ONC. As providers make decisions about which criteria to defer, are you thinking about ways that we could track and understand that midstream? It seems to me that it would be very instructive to understand which criteria they're deferring so that ONC could target maybe some of the REC outreach and other kinds of education resources to providers, but it would seem to make sense to do that well before the end of stage one.

**Farzad Mostashari – ONC**

Yes. Absolutely. I think one of the tensions here is that we really want to be able to learn from the experience in stage one empirically as we certainly ... finalize the next rule and hopefully even earlier than that, being able to provide some of that information not only for us operationally with the extension centers, as you point out, but also to the policy committee in your deliberations. So we have agreement with CMS that we would be reviewing and analyzing the information in the attestations in 2011 on the

Medicare side. On the Medicaid side, there's more of a dependency on the stage four processing and turning over that. Tony, do you want to add?

**Tony Trenkle – CMS – Director of OESS**

Yes. One of the things, as we design a system, we need to look at what are some of the criteria we're going to use for audit purposes. What are some of the criteria we'd want to use for evaluation purposes? We'd been working with ONC on some of the areas that they would be looking at and we would be looking at in terms of what are some of the things we need to refine for stage two. One of that obviously is to look at what comes in on attestations and what are some of the things that get deferred and a number of other areas that we need to look at and then correlate that with geographical and other areas where we can begin to look at what are some patterns or what are some deficiencies that we can either address through additional outreach or through possibly changes in the rulemaking the next time around.

**Neil Calman - Institute for Family Health - President & Cofounder**

Along the same lines, I think one of the things I had mentioned before was the ability to sort of separate out critical access, rural hospitals, other safety net providers and to monitor their rates of achieving meaningful use compared to the overall population. Hopefully we'll be able to get that. Again, I think it's going to be really important that we get that early on in the process so that we can see what happens. As the program rolls out, what happens, not wait until the end of the first year, because if there's some intervention that's needed there in terms of a special focus on those populations, I think we need to be able to implement that sooner than later.

**Tony Trenkle – CMS – Director of OESS**

Yes. I think there are several points there, Neil. One is, of course, data that we get in. The other is the feedback we get from the outreach efforts, the inquiries we get in, some of the work that we and ONC are going to be doing with the various communities, so we should be getting some of that feedback in pretty early, and I think then we can begin to look at ways to deal with that.

**Neil Calman - Institute for Family Health - President & Cofounder**

Are the states required to report to you the same data that you're going to have on people that qualify under Medicare? Are they required to report that? If so, how often?

**Tony Trenkle – CMS – Director of OESS**

Yes, the states are required. They're going to be required to report to us. I don't have the exact timing. I don't know if it's every day, but it will certainly be on a very regular basis. We'll have linkages between us and the states obviously because the people who register for the program will have to register through the central, national level repository that CMS will be running, so we're going to have two-way coordination with the state programs, as well as, of course, linking with ONC in the regional extension centers.

**Deven McGraw - Center for Democracy & Technology – Director**

I also thought that you all did a fantastic job in trying to balance the concerns that folks had about the bar being set too high with the real need to sort of push this forward. I think it's not going to surprise you. I was disappointed in the privacy section. Retaining privacy and security is a foundational and mandatory objective was important and certainly maintaining the requirement to do a security risk assessment and clarifying what it means to have to address deficiencies was an important step forward. But what was most concerning to me was some language in the commentary that seemed to suggest that there wasn't much that we could do in the future in terms of setting some measures and objectives in privacy to actually meet that goal. And I'm hoping that I'm reading this more broadly than you intended.

But it says we don't believe meaningful use of certified EHR technology is an appropriate tool to insure compliance with baseline privacy rules like HIPAA, and we don't think we should use the meaningful use criteria to impose different, yes, absolutely not different criteria than HIPAA, but no additional privacy or security policy requirements from those already required in HIPAA. If we're not using meaningful use to help enforce HIPAA, and we don't want to impose any additional criteria, then what's the universe of measures and objectives that are left to support the foundational objective of privacy and security? It feels like we are taking off the table an important tool for advancing best practices in this area.

**Farzad Mostashari – ONC**

I think you're right that we can't take off the table at this point anything, not only on the meaningful use side, but also on the certification side, things like automated encryption as an example. I think we should be careful not to read too much into that section.

**Tony Trenkle – CMS – Director of OESS**

Let me just address that a little bit further, Deven. I think there are a couple areas to think about here. One, of course, as Farzad said, is on the certification side. We need to insure that the functionality is built in to provide the ability to do the safeguards that a risk assessment or other types of assessment you do as a covered entity to insure that you have the privacy and security safeguards set in. That's number one. You have to have the ability to do that.

Secondly, where we can define in meaningful use criteria that's consistent with the privacy rule that's out there now and other ways that we can measure, audit, support, etc., of course relying on recommendations that your workgroup will be giving us as well, I think we certainly support that. I think the point is getting to that area and making sure that what we do is consistent and provides something that can be obtained and can be audited and can be achievable. I think to put language in that does not do that defeats the purpose and just creates ambiguity and confusion. So I agree with you. I think we've said before, and we certainly will walk the talk through these regulations and future regulations, but privacy and security are a bedrock. And, as one of the congressmen said to David and I yesterday, if you don't get it right, it will screw up the entire movement of electronic health records and information technology. We recognize that just one big screw up in that area could set us back for years, so we recognize it from both a practical standpoint and also as a policy framework.

**David Blumenthal – Department of HHS – National Coordinator for Health IT**

Let me just add to that I personally don't see this as off the table at all. We're anxious to find ambitious but achievable uses of meaningful use that protect the privacy and security of health information.

**Connie Delaney – University of Minnesota School of Nursing – Dean**

This is Connie Delaney. May I speak now?

**David Blumenthal – Department of HHS – National Coordinator for Health IT**

Sure. Actually, let me just take Gayle, who I suspect has a followup comment on privacy and security. Keeping us honest as always, Gayle. Then, Connie, we'll go to you next.

**Gayle Harrell – Florida – Former State Legislator**

First of all, I want to thank Deven for her comments. If you had not brought that up, I certainly was going to do so. I think, as I have said again and again, if you don't have the public's buy in on privacy and security, and if you're making a statement such as the one that appears there, there's a message in that, and I was disturbed by that message. When people read that, they may assume that we're not really serious about privacy and security, so I think your statements today perhaps clarified that some, and thank you for that. But I want to make sure that this group, and I know our privacy and security tiger team

is very cognizant of what is going on out there in the public, and we have got to make sure that we do assert every ability that we have, every lever, policy lever, and rule lever that we have to make sure that we have privacy and security.

There's another issue that if I may address also in reading this, first of all, I want to say thank you for hearing the flexibility and hearing the public and the outcry, and I know I certainly heard it in my community and across the state of Florida, as to the constrictions that were placed within the first, you know, the NPRM. This is a much broader, more flexible definition and use of meaningful use. However, one of the areas that I was quite concerned about is in moving just to core measures and not having specialty measures, we are really making it extremely difficult for some specialists to qualify. My goal, and I believe it's everyone's goal is to make sure that every patient has an electronic health record, and all providers are out there able to participate in the program. We want to make sure that we have as much of our population covered as possible.

When I look at some of the core measures, they don't fit into really what a lot of specialists do. I don't know many orthopedic surgeons who take BMIs. I really don't know many ophthalmologists who really routinely do height, blood pressure, weight. You know, those things just are not in the normal practice in many, many specialties. Smoking cessation, these kinds of things just, you're going to be really requiring additional burden on a lot of specialists. And we had a whole day of specialty hearings, and I thought we were moving down the right track and listening to what some of their concerns were.

Then even in the menu options, there are many specialists for whom there are no menu options. My questions is, does that mean if I'm a specialist that none of those menu items work for that I don't have to report on anything. You know, you say specifically, for instance, a chiropractor doesn't have to report on e-prescribing with a denominator of zero or a dentist doesn't have to report on immunizations. What does that mean if, for instance, there are no menu items that really apply to me?

#### **Tony Trenkle – CMS – Director of OESS**

You mentioned a couple things, Gayle, one on the privacy. Let me reiterate again. As CMS's senior agency official for privacy, and who I signed about 200 privacy impact assessments several weeks ago. It was a stack this high. I'm definitely cognizant of the need to insure we have privacy and security, and we'll reiterate that, and certainly work closely with the committee and the workgroup to make sure that future meaningful use requirements and certification requirements are reflective of the needs that we have.

You asked the question about, I think you asked two questions, as a second question. One sounded like you were starting with the clinical quality measures, and then you moved to the structural measures, so let me start with the clinical quality measures first. On the clinical quality measures side, as you know, in the NPRM, we did divide it up by specialty. We had measures in there that were not electronic specifications. We had measures in there that a number of subspecialists and others wrote to us and said they did not see their specialty in there. We heard from a number of organizations who felt that we should not be dividing it by specialists. For this rule in the quality area, we did take out specific specialty measures, again, a set to choose from as applicable to their specialty.

The process, we recognized needs to be worked with. We've got an HHS task group that Farzad actually is part of and maybe can speak more to that will hopefully help us work through some of the issues we found in this stage one area with the clinical quality measures. Now I'm assuming you were talking just about the quality measures, or were you talking about the structural measures as well? I wasn't clear in terms of deferment.

**Gayle Harrell – Florida – Former State Legislator**

I have a concern about both of them and where we're going with how— We want to make sure that every specialty has the ability to qualify.

**Tony Trenkle – CMS – Director of OESS**

Right.

**Gayle Harrell – Florida – Former State Legislator**

My goal is to make sure that every patient has the ability to have an electronic health record that all their doctors have access to and can use and that all their physicians qualify. I don't see the delineation or perhaps we're not giving the ability to some of our specialties to be able to qualify.

**Farzad Mostashari – ONC**

You asked a specific question in terms of if I have a zero denominator for all of the options that if there is such a provider who can say I have a zero denominator for all of—

**Gayle Harrell – Florida – Former State Legislator**

Correct.

**Farzad Mostashari – ONC**

--not just that I can find three that I have a zero denominator for, but that all of them have a zero denominator for, I don't believe they have a requirement. I mean, the denominator is zero, and the numerator is zero. That's what they would report, and there wouldn't ....

**Gayle Harrell – Florida – Former State Legislator**

But they have to qualify. They have to have some menu items that they have to qualify.

**Tony Trenkle – CMS – Director of OESS**

Well, if such a case occurred, it would seem like they wouldn't be able to qualify in other areas as well.

**Farzad Mostashari – ONC**

I think it's pretty hard to imagine someone who literally would have a zero denominator on all of the menu items. I believe, Tony, correct me if I'm wrong, if on the core measures they literally have a zero denominator for – they have a non-zero denominator for fewer than three, can they report fewer than three on the core?

**Tony Trenkle – CMS – Director of OESS**

Yes, for the quality measures. Yes, that's correct.

**Farzad Mostashari – ONC**

On the quality measures.

**Tony Trenkle – CMS – Director of OESS**

They look at this. There's the three core, and then we have the three alternate core. If out of that six, they can't report three, yes, they could report less.

**Farzad Mostashari – ONC**

They could report fewer.

**Tony Trenkle – CMS – Director of OESS**

Now recall, with the quality measures for this particular stage, it's reporting. They're not being measured on the numerator and the denominator. They're being measured on whether the report a numerator and denominator, so there's not a percentage threshold associated with the quality measures.

**Farzad Mostashari – ONC**

But I want to point out two things. One of them is, I think we made it more flexible by removing the set, the specialty specific sets. So now they have a broad range to choose from instead of having to report all of a particular set. They can choose among that.

The second issue there was the feedback we got that there have to be electronic specifications for the measures. Given the current process of retooling and NQF endorsement and so forth, we were only able to get the 44, I think, measures that's listed there with electronic specifications ready. So we did not want. So while we would have liked to have more measures there, we felt that the imperative was to make sure that there were electronic specifications available.

Obviously this is a situation that is going to change. It's going to have to change for stage two. Not only do we need to have, make sure that there are measures for all the specialties that are appropriate for them, we need to have better measures, and that means having measures that are high impact, measures that are health IT sensitive, and measures that are parsimonious so that we have, and I'll give you some of the things that this group talked about, closing the loop on referrals, which is broadly applicable to specialists, but is not particular to any one specialty: medication safety, medication adherence, patient engagement. Those are broadly applicable, parsimonious measures that are going to be the kinds of measures that we want to move towards and also measures that take advantage of the full strength of the electronic health record, things like measuring improvements over time, not just how many people or what percent of people did you test a blood pressure on or BMI on, but what are the trends in functional status of your patients over time. I think, on the quality measure, we had a lot of work to do, and we need to do it very quickly.

**Tony Trenkle – CMS – Director of OESS**

And also point out that this program is not the only program for quality measures either. We have a number of programs, some of which are CMS, some of which are other programs. But we have programs in the Accountable Care Act. We have programs, the PQRI, the RAC DIPU, CHIPRA, so we have a number of areas where we can influence and make sure that quality of care is improving, and I think that one of the things here is not to get too caught up with what is in the meaningful use matrix without recognizing that is just one of many quality programs that are out there, and they all need to be looked at. They need to be integrated as much as possible and coordinated above all. I think that's the challenge. The electronic specifications is one piece of that, but it's by no means the only issue when we're looking across various quality programs.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Honoring David's commitment to you, Connie, you're up next.

**Connie Delaney – University of Minnesota School of Nursing – Dean**

I too want to congratulate you, Tony, on the excellent work and the degree of flexibility and responsiveness to comments. I particularly want to comment on this approach beginning to support and empower the baseline for prevention and health orientation. And my question to you is, do you and/or David anticipate a significantly meaningful communication to the public that recasts this work from the perspective of the patients, families, and communities? I'm particularly reflecting on the consumer input a couple months ago asking for meaningful use actually being refocused less on the technology, etc., and

more on the people and health. Basically I think that's been accomplished, and it is a communication issue. Can you comment on that?

**Tony Trenkle – CMS – Director of OESS**

Yes. I think, as you saw, Connie, we did make some changes in the final rule to reflect the consumer side, and I think that's an area that we need to spend more time on for the next several stages. I've likened if we just focus on the provider side, it's like focusing on the pilot of an airplane without taking into account the passengers. I think the point is there's a lot of areas that we can look at for future stages, some of which is education and resources, some of which is linking with other consumer related online and other services such as personal health records. I think these are areas we need to be taking a much closer look at over the next several stages.

Then the second part is how do we message that? Part of this is, you don't want to get perception ahead of reality, and we all need to recognize this is a work in process, and there's great advantages of electronic health records and the ability to make major changes to the healthcare system, patient safety, other areas, but I think it's critical that when we message that, we message it in a way that reflects the reality and where we're going, but doesn't create a perception that's not matched by that reality. I think I've seen that in my own cases just with electronic prescribing where the perception and the reality sometimes diverge because the infrastructure is not always there to support it the way it is purported to be in some cases.

**Farzad Mostashari – ONC**

Yes. Connie, thank you for that. I do think that it's really important for us to be able to communicate clearly what does this mean for you as a patient, and how is this making your life and your healthcare better, safer, higher quality, and how will you feel it? I think there are some things that are going to be more obvious than others in terms of having an after visit or after discharge summary or being able to access your own information. But I do think that we need to not only do it, but also be able to communicate better what this means for people. I'm going to make one plug now, which is, to help us do that, we are recruiting at ONC for what we call our consumer ... who can lead the work of the consumer e-health agenda at ONC, and anyone listening out there who is interested, go to our Web site.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Charles?

**Charles Kennedy – WellPoint – VP for Health IT**

Yes. Tony and Farzad, I want to echo other's compliments about achieving the right balance between setting the bar high enough to get value and offering the real world flexibility necessary to make this move forward. I do have three questions. The first one is in the area of clinical quality measures. As you look to satisfy some of the alternate core measures such as immunizations, are there any restrictions on the use of claim data as a source to satisfy that requirement? We typically get a claim when an immunization is performed, and I wondered if that could be one of the data sources for satisfying that measure.

The second question is, will the clinical quality measures be made public? And, if so, at what level: at the individual hospital level, doctor level, what? And then third, if you could give me a little bit more background on the rationale to drop the administrative transactions. I mean, I think that was the right answer, but it would be helpful to understand the thinking behind that.

**Farzad Mostashari – ONC**

Sure. In terms of the use of claims data, there are some events for which claims data is likely to have even better quality, higher quality data, more comprehensive information. And the integration of

administrative information or clinical information for the purposes of quality reporting is obviously a goal. The challenge is going to be to make sure that this is meaningful use of certified EHR technologies, so the quality report has to be generated from a certified EHR technology or a module thereof. If there is a registry or quality reporting system or data warehouse that the hospital or provider is using to fulfill their quality reporting and it is certified as such, then that database, data warehouse can certainly include information from both the medical record, as well as from claims received. There's no limitation to that, but I do want to stress that it can't be that they simply say, okay, my health plan told me that this is what the quality measure was. It has to be coming out of certified EHR technologies.

**Charles Kennedy – WellPoint – VP for Health IT**

Right. So if we sent a file to these various hospitals, it was incorporated into their EHM, that would be acceptable.

**Farzad Mostashari – ONC**

That's right.

**Tony Trenkle – CMS – Director of OESS**

Yes.

**Farzad Mostashari – ONC**

In terms of whether it's made public, I'll let Tony take that one.

**Tony Trenkle – CMS – Director of OESS**

We haven't made a decision on that at this point whether it'll be made public or not. There will be some information. Obviously we're required under law to make public in terms of who qualifies for the program and things of that sort, but we haven't made a decision on the data, which that will become public or not. Obviously there are privacy considerations and other considerations involved in that.

The administrative transactions was one that received a lot of interest within the government. There are a number of people outside the government who also have varying opinions of it. A number of people wrote in and this should not be included. It's not part of an EHR. It's administrative. It's different systems for the most part that utilize that from a certification standpoint. It makes it much more difficult to certify.

On the other side, we had people who said we need to bring together the administrative and clinical side. These are efficiency measures that are touted in the Affordable Care Act. We have a number of major administrative transaction initiatives already going on with 5010 and ICD-10. So we decided, for this particular stage, we would defer them because of the comments that largely came from the community of hospitals and professionals who would be reporting. But we did signal our intent for future stages that we would like to include the administrative transactions because we do consider them to be critical in a number of areas, and it's also part of this, as I mentioned the quality area earlier, is a way to begin to harmonize and coordinate initiatives across the spectrum. With ICD-10 coming in, which kind of touches both the administrative and some on the clinical side, it allows us an opportunity, as we move into 2013, and with 5010 going in, in 2012, we have an opportunity now to begin to look at these as part of the critical core of meaningful use objectives.

**Farzad Mostashari – ONC**

A couple things in terms of in addition to the legal concerns, confidentiality concerns that Tony mentioned, the other consideration that will go in there is the understanding that this is a process and quality measurement and accurate quality measurement is a journey, and what we're asking folks to do is to start on the journey. We understand that the first time you measure quality from within your system, you look

at it, and you say, well, this isn't right. And it's that process of looking at it and saying what's going on. Is it how it's coded, which is usually not the only issue is how it's configured.

It's where people are their workflows? Is it how people are entering the data? Is it all the different things that go into this? We want to be sure that when there is public reporting, that it really reflects the true quality of care and not to do so prematurely, but yet not to kind of say we're not going to have it as a meaningful use requirement until it's perfect because then we would be waiting too long, and people don't really start on the journey until they come face-to-face with that.

On the administrative transactions, there's also a certification piece to this, which is that there is, as was pointed out to us in the comments, and the comments really do make us much more informed and smarter. There is a switchover right in the middle of meaningful use stage one of the 4010 to the 5010 transactions. That may seem like something that would be easy to deal with, but it has profound implications.

Specifically, the scenario that we were made quite aware of is that there may be many providers who are currently using practice management systems that haven't been upgraded for many years, and the vendors would no longer – knowing that they have to upgrade and the 5010 is coming, would not go out and seek certification for those older products. And those older products probably wouldn't meet the certification requirements of 5010. So we would be in a situation where there would be potentially a large number of providers who would be relying on existing practice management systems interfaced with their EHRs wherein those modules would not get certified, and they would be not able to become meaningful users, even though they're doing everything right. That was another part of the complexity of the standards transition in certification of practice management systems, but we think that actually with the administrative simplifications requirements in the Affordable Care Act, and with the required upgrades that all these systems will need to take, it's actually a good time in stage two to introduce those requirements.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

I have a couple of clarifying questions. One is, you talk about signaling your intent in the preamble or the commentary, response to comments, there were a lot of –will”, like it will be in stage two and CPOE will go to 60%, etc. Are those –wills” future tense signals or are they a certain prediction of the future?

**Tony Trenkle – CMS – Director of OESS**

Wills, should, maybe, all of them are signals, but it signals our intent to move in that direction. Obviously if we go out in rulemaking and we get strong public comment against doing that, or if we see that the infrastructure has not advanced enough or other reasons, we can— It's not binding because it is not in the reg language, so it's not a binding requirement. But it does signal our strong intent to move in that direction, but obviously in two years, things can change, and at that point we may need to modify.

**Farzad Mostashari – ONC**

The one exception—

**Tony Trenkle – CMS – Director of OESS**

Is the CPOE, which did end up in the reg text as—

**Farzad Mostashari – ONC**

Sixty percent.

**Tony Trenkle – CMS – Director of OESS**

At 60%. Of course, reg tests can also be changed by rulemaking as well.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Okay, so all of those forecasts are signaling intent and not necessarily cast in concrete yet.

**Tony Trenkle – CMS – Director of OESS**

No. Will is much stronger than should though.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

They did say “will”. And the second clarifying question is, you also mentioned that you reserved the right to change the stage on criteria. Are those only fixes, or they could be substantive in terms of adding new functionality? What was behind that statement?

**Tony Trenkle – CMS – Director of OESS**

As you recall, we had this discussion in the policy committee a number of meetings back, Paul, and I think there's a recognition that the infrastructure in 2013 or 2015 is not going to be the same as it is today, so from that perspective, we would need to look at the stage one requirements and see if they made sense. For example, the one for information exchanges to perform one test, hopefully that's not the bar for stage one in 2015, or we're all going to be in big trouble.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Very good. Paul?

**Paul Egerman – eScription – CEO**

First of all, I want to, like everyone else, congratulate you and say that you do a really fantastic job, and it's certainly an example of government work in the way it should work in terms of the amount of outreach and the responsiveness that you've showed to people's concerns. I had some comments about the section on standards and certification. As Dr. Blumenthal said, you did a good job of being responsive to the standards committee by being more specific, and so I thought that was good. But the approach that you took still limits what you've done in standards and certification to those things that are included in the meaningful use criteria. By taking that limiting approach, I personally think you were missing an opportunity because fundamentally with the whole certification process, that's a very powerful public policy tool.

Deven made some comments about privacy and security, but it could also be used for improving interoperability, which is certainly something that's clearly called out in the legislation, and so I personally would like to have seen more, for example, with laboratory results, results interfaces, and more content standards there, even if they're not required for meaningful use stage one. My question is, as I look at stage two, can we put that for future steps? We list all these things for what we want to do in the future for meaningful use. But for stage two, can we be looking towards increasing the standards and certification criteria to improve interoperability and also to reduce barriers to adoption for issues that may not be called out in the meaningful use criteria, but could be very significant problems that are making it harder for physicians to adopt these systems?

**Farzad Mostashari – ONC**

It's a great point. I think it touches on our strategy for interoperability moving forward. The recommendations from the adoption and certification workgroup around certification were to really make them not the laundry list of all the things that an EHR should be and to make them really focused on the meaningful use. And we kind of took that to heart as kind of a core principle that it's meaningful use of certified EHR technologies, and that the certification, while I don't think it legally need to ... you're

absolutely right. As a principle, we limited the certification criteria almost entirely, almost entirely to issues that were directly connected to a meaningful use requirement, so we'd have the meaningful use requirement, what you have to do, what you have to have in order to do that, and then what are the standards that would appertain to that certification criteria?

I do think that this gives us a lot of leeway in terms of lab results. Absolutely we could include that. That is part of the meaningful use. The content standards, anything that's in the summary of care record, we can come up with vocabulary and terminology for that. I think there is a lot that we can do through there. As we think about stage two, this came up with the issue of device nomenclature. If the standards committee is to advise the administration on device nomenclature, do we need to have a corresponding meaningful use requirement in order for them to do that? If not, what is the governance authority and mechanism for not just adopting a standard, but then actually disseminating that standard and having the lever to effect the industry absent certification? I think that's very thoughtful and, I think, something that we need to consider.

**Tony Trenkle – CMS – Director of OESS**

I think, also, to be cognizant of the fact that we had a very limited time period, and we had to have the two regulations synch together, and if something had gone into the standards and certification reg that would have caused a delay of any sort, it could have impacted the whole first year of this program. But I do, as Farzad said, recognize the need to look at whether this can be used as a lever to improve other types of standards and certification areas that may or may not be directly connected to meaningful use.

**Paul Eggerman – eScription – CEO**

I appreciate those comments, especially if you look at stage two, if what's happening is we're raising the bar on users by going from 40% to 60% on some items. We should also raise the bar on vendors in stage two by asking them to do more because the vendors also are benefiting significantly from this process, and so I think stage two could be a good place to do that, so I appreciate those comments.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Judy?

**Judy Faulkner – Epic Systems – Founder**

Be really careful that we keep creativity and initiative there, and this group does not become the definition of EHRs for the future because I don't think they'll do as good a job.

**Tony Trenkle – CMS – Director of OESS**

Yes.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Any other comments or questions? Good. Thank you very much, again, for terrific work in coming up with the final rule, and thanks for your questions and answers. Thanks.

**Farzad Mostashari – ONC**

I want to thank all of you for being such an integral part. This was a terrific process.

**Tony Trenkle – CMS – Director of OESS**

Absolutely.

**Farzad Mostashari – ONC**

As someone new to the federal government, it was quite the journey, but I think the output of this, the outcome was, I'm proud of. I think it's a terrific product, and I really thank you for being such a critical part of the process.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

We'll move from one part of the government to another update from ONC with Doug Fridsma. While Doug is coming to the table, I was remiss in not asking for approval of the minutes. Thank you, Scott. I want to go back to that and ask whether people had a chance to read the minutes and if there's any motion to approve the minutes.

**M**

(Inaudible.)

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Any discussions, corrections? All in favor?

**M**

Aye.

**M**

Aye.

**W**

Aye.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Any opposed to abstained? Thank you. Doug, take it away.

**Doug Fridsma - ONC**

I do not have slides today, and in part just to try to be brief today with the updates that we have from ONC and some of the activities. That allows us to focus a little bit on the regulations that just came out last week, and maybe we'll make up a little time today as well. I just want to thank the committee again for all the work and echo the comments that Farzad had. This has been, again, as someone who is relatively new to this role in the federal government, this has been quite a journey, but it's been a good one, and I appreciate all the work of this committee.

I just want to state a couple of updates. The first is around the standards and certification rule. Next week, when we have our presentation to the HIT Standards Committee, we'll go into a little bit more detail. But I just wanted to mention that one of the biggest things that we got from this committee in terms of feedback was to increase the specificity of the recommendations, in large part to make it easier for us to test and to certify against, and also to move closer to the goal of having interoperability. I think, to be able to have interoperability, we need to have increasingly constrained sets of standards that allow people to know that when the information is sent from one place to another, everybody is using the same protocol or the same result. I think that's been probably the biggest change that we had within the standards and certification rule.

We did also remove one of the transport standards around REST and SOAP. In large part, we've had a lot of experience in the industry thinking about innovative ways in which we can move information around, and the question was asked, do we limit our ability to get to interoperability by not defining that? I think

the answer was that we don't have to, at this point, declare REST or SOAP or a particular transport. I think we can still achieve interoperability and innovation without doing that.

We did some clarification of value sets so, for example, within the smoking regulation, we tried to provide, again, more specificity there to try to get us more information. And with regard to privacy, privacy and security, we adopted a more specific set of standards that were recommended by NIST and that sort of represent best practice for privacy and security as well. And so, we tried to take all of the things that you folks have told us about in terms of innovation and making sure that we have privacy and security, and that we move towards interoperability in terms of our implementation specification. We'll have more to say next week, as we sort of present to the HIT Standards Committee with that as well.

One of the things that now has happened is we have a final rule for the certification process or for the temporary certification process, we have a final rule for the certification criteria, and we have meaningful use. And so many of the things that now fall within the Office of ONC now is to operationalize a lot of the things that are going on. So last month when I spoke, I gave you an update or at least some information about the standards and interoperability framework that we are standing up.

We are in the final throws of getting our contracts awarded, and I expect that within the next two to three weeks, we should have the majority of those contracts awarded to stand up that interoperability framework. It's really an effort to try to, as I talked about last month, an effort to be able to move us through the lifecycle of standards and certification development. And so as we do that, we will probably come back to you in another month or so and give you some more information about where we are in terms of operationalizing the vision that we have around that.

Third is certification. I'm happy to report that we have received three part-one applications, and one that has completed both part one and part two of the certification process. We're in the process now of reviewing those for completeness to see if we are on track with those. And so that process seems to be working fairly well at this point, and we are anticipating that we will have at least one and probably more than one in terms of our ability to have these certification bodies, so stay tuned with that.

Then I guess finally with regard to the Nationwide Health Information Network, we have a couple of activities that are going on there. The first is with regard to the NHIN Exchange. There's been significant work that's been going on to support the presidential initiatives around the virtual lifetime electronic record and some pilots that are involving both the VA and the DoD. I think it will be interesting for us, over the course of the next couple of months, once we stand that up. Much of the work that's going on within the VLER project and within the VA and DoD is in some sense a federal beacon community, if you can think about it that way. They are working on the really hard problems around interoperability, doing things that haven't really been done before, and I think we will learn a lot with regard to that, that will help inform stage two and stage three when we think about what is necessary for us to achieve interoperability, and what are the parts that we need to really focus on so that we can take what we learn from the VLER project and sort of promulgate that more broadly.

We also had worked with the NHIN Direct project. That continues to work very closely with the tiger team to make sure that we're addressing some of the policy issues that are raised within that. Not much more to report with regard to that project. They are looking at moving to the next phase, which is to begin doing some pilot testing and to examine that a bit further as well. But that is, again, a project that we've learned a great deal with regard to the policy issues around it and what's the best way to have that kind of directed exchange.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Questions, comments? Paul?

**Paul Eggerman – eScription – CEO**

First, Doug, I appreciate the summary, which is an excellent summary, and obviously huge project is being made on a lot of fronts, and you're picking up on what Tony and Farzad said. There's just so much stuff happening here. It's hard to imagine going any faster. The comment though that Farzad made in his presentation is a very good one. The difference between adopting standards and disseminating standards, and certification is the vehicle to get it certified. So a comment or question that I made at our last meeting, and I'll make again is to what extent are we getting some of these things like NHIN Direct that were coordinated with the timing of what we need to do for stage two is certification. If we can include standards, message transport standards in stage two of the certification criteria, that would be a big step forward. But it's hard to coordinate all these moving pieces.

**Doug Fridsma - ONC**

I think there are a couple of things that we've learned. I think, first, as we're beginning to develop or identify standards that we want to use for the exchange of information, and NHIN Direct would be an example of that. There are other standards that we've identified that I think are useful. We need to make sure that, at the time that we're thinking about adopting that standard, that we include certification in our discussions. Certification shouldn't be an afterthought of either the adoption or the development of standards. It should be an integral part of what it is that we do. And so, one of the conversations that happened as we were developing the final rules is working with NIST and going through kind of what the standards and certification were and what the testing tools and methods that we could use for certification were provided a tremendous amount of clarity and made it clear where we needed to maybe push further with testing or maybe create more specificity so that we could do a better job with certification.

As part of the standards and interoperability framework, we're really trying to make sure that our certification and our partners at NIST are involved throughout this process and not at the very end after we've kind of done a bunch of work. And in fact, we need them to help us with developing the test beds and the testing infrastructure, and we need to make sure that those things are linked very closely to the implementation specifications and the standards that we adopt. And so I think, if we understand the importance, or we see the certification as one of those levers that we can use, including that in the conversations earlier in the process of standards development and adoption, I think, will help us know how to use that lever more effectively.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Any other comments? Deven?

**Deven McGraw - Center for Democracy & Technology – Director**

Doug, I just want to ask you a bit about the decision to make the accounting of disclosure standard that had been in the proposed certification rule into one that is voluntary. In reading through the commentary, it looked like you were – that perhaps a decision was made to allow the Office of Civil Rights to put some parameters around what might need to be included in such an accounting before finalizing a standard, in addition to giving the vendors some more time to build it into the products, but I'm not sure if I'm right about that. And since I'm not on standards, and I couldn't ask you that there, I would love to get some feedback on that here.

**Doug Fridsma - ONC**

I think, as David has articulated so well, privacy and security, accountability are critical things that we need to include in the rules. I think it's part of – we talk about the trust fabric. We talk about making sure

that people feel that they can trust the way the information is being used and handled. That's a critical part for the adoption and the use of information technology. So that remains a high priority.

I think there are still some issues that we need to work out that we aren't quite sure what's the best way to do things. I think there are policy issues that we need to address, and we want to make sure that those things can be discussed and sort of articulated before we start locking down a technology solution or a particular certification strategy to handle that. I suspect we will have to revisit this and, as we go forward in stage two and stage three, but I think it still remains a high priority for us to do.

**Deven McGraw - Center for Democracy & Technology – Director**

I mean, I'm not unaware of the enormous challenges to implementing this, but I just want to make sure it doesn't get on terminal hold.

**Doug Fridsma - ONC**

Good.

**M**

Could you give us a little bit of an update in terms of the progress and timeline around NHIN governance?

**Doug Fridsma - ONC** NHIN governance, yes, we are working right now to develop an RFI that will get us some additional information on this. I think we would like to understand both the scope of what we need to do within NHIN governance and kind of where within that scope we want to apply some of the governance levers. The current plan is that sometime in August we will have an RFI together, and then we'll need to go through the process of getting that out there. But we are actively working on that issue and likely come back to this group for some more input as well.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Along with that, would it be fair to ask a question about how the state HIE communities are doing and what is at the top of their list in terms of what you're hearing and the needs that either you or your asking the FACA committees to help provide some advice on?

**Doug Fridsma - ONC** I may not be the best person to ask about the state HIEs. Farzad? I don't want to misspeak.

**Farzad Mostashari – ONC**

We did a program information notice for the guidance for the state health information exchange programs and, in that, we provided some clarification in terms of what the expectations are for the state health information exchange grantees and the health IT coordinators specifically. One of the things that we pointed them to was meaningful use and that they should be really thinking very concretely about how what they build today can help providers succeed in achieving meaningful use and to focus on specific transactions, to understand the gaps in their states in terms of the ability of the trading partners of providers to participate in electronic exchange with them, recognizing that meaningful use really is only a lever on the providers, and if the providers are dependent on pharmacies, laboratories, health plans, public health departments to be the other end of the handshake, that we need to use all of our policy levers and technical assistance and convening and so forth to make sure that the handshake can occur.

We've asked the health information exchange grantees to conduct GAAP analyses within their states to identify what are the critical gaps to use what's already there, build on what's already there, and to use all of their potential levers to come up with a strategy for addressing those gaps. We have some wonderful examples of that. Jonah, someone we all know and love, in California, they put together a proposal, for

example, to look at the small community laboratories who cannot participate in standards based or difficult for them to participate in the standards based electronic delivery of lab results and to provide a service for them.

One of the things we've clarified is we understand that the amount of funding that we have available for the state health information exchange program is not sufficient to create de novo, comprehensive, interoperability solution for every provider in the state, for every kind of exchange, and to sustain that. We recognize that there is no guarantee of additional or even a likelihood of any additional funding for this activity. So people have to be incredibly strategic in terms of understanding what is already there in their states, how they can use all of their coordination of all of the, whether it's Medicaid, public health funding, and state levers, and how they can strategically fill gaps in doing that. In some places, that's going to mean statewide health information exchange as a noun. Delaware, Vermont, and others may be able to do that, and already well on their way. In other places, it's going to mean much more limited focused strategic investments.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Gayle?

**Gayle Harrell – Florida – Former State Legislator**

While we have you all up there, can you give us an update on the RECs?

**Farzad Mostashari – ONC**

Sure. The regional extension centers are doing well. We are having the regional meetings. We have selected 60 regional extension centers. We are seeking – there are only three little areas in the country, including one that you're familiar with, that are absent currently the support of a regional extension center. We do cover about 95% of the U.S. population right now. There's someone for the docs in that area to call. In the gap areas, we are putting another solicitation to fill in those final gap areas. Our goal is to have 100% of the country covered.

Now the question of covered with what is the right question. We are working to increase the capacity of the regional extension centers, to bring them online. There are some who are obviously more capable who have more of a track record, who have more staff in place than others.

One of the main messages that we're establishing in the culture of establishing with the extension centers is that all knowledge is local and that the best source of information for the extension centers is probably each other and to create the communities of practice around the specific activities that they're doing, whether it's outreach, whether it's vendor selection, whether it's the privacy and security, whether it's project management and so forth for them to work with each other and to learn from each other.

We are going to be providing some technical assistance. We're going to be providing materials. We're going to be providing an infrastructure for them to convene. We're going to have regional meetings, but ultimately it's going to be the local knowledge that's gained and learned. But they are not only our hands in the field, but also our eyes and ears, so we really need, the extension centers, as they keep coming up in a variety of conversations, they're a critical part of the infrastructure, and we have to get this right.

**Doug Fridsma - ONC**

Just a follow-on to that, as it pertains to the regional extension centers, are other providers of implementation or adoption, as we're going forward, what is ONC's initial read on what we believe is going to be a big issue is this workforce and finite capacity to deliver these? Do you have any early read

from ONC that you could update us on, on activities around workforce or any feedback that you're receiving from these groups?

**Farzad Mostashari – ONC**

Yes. We also have the workforce program, four of them actually. Look, in the long-term, if there are good jobs in the sector, people are going to get trained and fill those jobs, but that's in the long-term, and so there is a transitional period. I know people who can't get into a class in a community college right now because all the courses are full.

One of the things that we are trying to accelerate now is the development of a curriculum that can take people who have a health background and fill them in on what they need on the IT side, or people who have an IT background and fill them in on what they need to understand in the health system to be able to effectively staff not just the extension centers, but also the hospitals and the doctors' offices and the vendors who are going to need those skill sets. We hope that as early as this fall, we will begin having the community colleges funded through the community college workforce program begin to be offering courses, and we're developing proficiency exams and so forth, so there's a whole series of activities going on that we can update you on more fully. But it is really aimed at accelerating and filling the transition.

**Doug Fridsma - ONC**

Just a follow-on, and to that point because I think this is going to become quickly a big issue for us, but is there a good awareness or is there an awareness of the skill sets for the technical part of this, but also for the applied part, as we proceed towards meaningful use, as you all are aware or we need to be aware of the people who actually do the training and transition and process transfer to the providers typically end up being peer level medical professionals of that sort. Is there an awareness of that because both sets are equally very important?

**Farzad Mostashari – ONC**

Yes.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Anything else? Wonderful. Thank you very much. Thanks, Doug and Farzad.

**M**

(Inaudible.)

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Actually, we're going to move on to the enrollment and workgroup update, and I think Doug is going to play another co-role with Sam. Sam, are you on the phone?

**Sam Karp – California HealthCare Foundation – Chief Program Officer**

I am. Yes. Good morning.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Great. Who is going to start out?

**Sam Karp – California HealthCare Foundation – Chief Program Officer**

I'm going to start.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Thanks.

**Sam Karp – California HealthCare Foundation – Chief Program Officer**

Good morning, everyone. As I know you've heard from David and Aneesh in the past, this workgroup was formed to develop standards and protocols that facilitate enrollment in federal health and human service programs, as required under section 1561 of the Affordable Care Act. While our emphasis has been on simplification and streamlining of healthcare enrollment, there's also been a focus on the reuse of eligibility data, as appropriate, to enroll individuals and families in a range of programs for which they may be eligible. Our charge has been three fold: to inventory the standards in use, to identify gaps, and to recommend candidate standards.

I'm pleased to report that we're making progress in conceptualizing a set of minimal standards, services, and data elements that we believe would work across a variety of use cases and architectures. At a meeting, the workgroup meeting that we had on Monday, just two days ago, a set of very preliminary proposals came forward, and I'm going to review them for you this morning at a high level. These recommendations, I should be clear to say, will be further vetted and refined over the next month. So you should have a deck there. I assume everybody has a deck on this topic. Do you?

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Yes, we do.

**M**

Yes, Sam, and I can run the slides for you.

**Sam Karp – California HealthCare Foundation – Chief Program Officer**

That's great. If you move to slide three, you've probably seen this list before. It's a reprise of the principles that we've kept in mind, keeping it simple. Don't let the perfect be the enemy of good enough. And keep the information cost as low as possible, and we're certainly not trying to create a one size fits all standard.

If you move to the fourth slide, let me give you just a high level update of the enrollment workgroup activity. We've had three workgroup meetings to date. The first was held six weeks ago, June 14<sup>th</sup>. We had a meeting on July 2<sup>nd</sup> where we realized we needed to focus on specific components, and we created four tiger teams, which I'll review in a minute below, and then the third meeting we had, which, as I mentioned before, was just Monday of this week. So the tiger teams have been activated. One on working on verification interfaces, one on business rules, one on plan benefit handoffs, and a fourth on privacy and security. Most of the presentation I'm going to go through and give you the sense of the preliminary recommendations that are coming forward.

Then I'm going to ask Doug to talk about the NIEM data harmonization project that he is leading, which is underway. I'll come back and just give you a summary, a brief summary of some of the feedback that we've received from public, from states, from other organizations through our FACA blog and that Aneesh and I did, and also some other feedback that we received via e-mail and letters. Then, finally, I'll close it out with just giving you a sense of some of our next steps. Before I go further, and so it doesn't get lost at the end, I want to just mention the tremendous support that our workgroup has received from ONC staff and the consultants they've assembled. We have a tremendously engaged participation by our workgroup members and are working extremely fast to try to get this job done in the September 30<sup>th</sup> timeframe, which we were handed.

If you move to the next slide, I'll start walking through where we are with preliminary recommendations in each of the four areas. We have a verification interfaces tiger team, and their charge is to develop a way to modernize verification interfaces to help determine eligibility in an expeditious manner and to come up with requirements for something that we started calling a verification hub, but I think we now move to thinking more about it as being a business service. We see electronic verification as a key element in simplifying enrollment, simply removing the burden from the applicant and putting it much more on the system. We'll talk more about that in a minute.

If you turn to the next slide, slide five, you'll see that there are actually three verification sources that are required by the Affordable Care Act. Section 1411 requires that individual eligibility be verified through interfaces with three specific federal data sources: IRS for income, Homeland Security for legal residents, and Social Security Administration for citizenship. We've had public testimony from each of these agencies, terrific cooperation from them and from others trying to understand exactly what their current and future capabilities are in this area to be able to provide these kinds of services, and we've had a lot of focus on what is the currency of the data and what is the completeness of the data that they can provide.

Move to the next slide, so the beginning set of preliminary recommendations for electronic verifications are the following. We're going to start with the three required verifications as base verifications. We think these interfaces should provide, where possible, real time verification. We heard from SSA that they already have that capability. There's a capability within IRS in a demonstration project currently with student aid applications where it's being provided in real time.

We think that, ideally, Web services should be the transport for being able to provide this service. Where possible, we would use NIEM compliance exchanges. But recognizing that there are an awful lot of legacy systems out there in the states that there would need to be translation service to support the data exchange of the verification results with these legacy systems. Here we propose to use some pretty standard transmission formats, HL-7, XML, etc.

It's important for our workgroup to think about the data associated with these verification interfaces need to be disaggregated by individual rather than family size because the eligibility rules for healthcare programs and some of the other programs, SNAP for example, food stamps, you need individual household rather than a group in a household. The data associated with these interfaces, we believe, needs to be reusable for some of these other eligibility decisions, and they need to be as clean as possible and ... in order to get reliable matches. We heard testimony, for example, from the Social Security Administration, that in using just a minimum set of core data elements in working with 26 states in the CHIP program, they have a 94+% match on citizenship, and this an overnight batch process.

Then the last point on the verification interface is back to this idea of developing a verification service construct. Ideally that would allow for a development platform so that this type of a service could be built once or a set of specifications for in construct, in boundaries could be designed so that it could be used for both a federal level and state exchanges and even Medicaid and other programs. The goal here would be to try to at least design it, if not build it once, not 50 different times. Essentially, we look at it as a potential shared business service.

Let me move, and I'll move through some of these others quickly, and then we can go back and have questions on any of them. The second tiger team worked on business rules, and their charge was to develop recommendations to create some standard formats and tools that would allow us to consistently express eligibility processes and rules across states. This is much more of a work in progress, while some of the other standards are being finalized because it needs to take into account the relationship

between the security, verification data standards, and so on, and I think you'll get a sense of this better when Doug describes the NIEM mapping work that's going on.

The recommendations, again, preliminary coming out the – move to the next slide, ten, on the business rules recommendations is again back to adopting consistent expression of whatever the business rules are to be so that we can provide for more efficient updates, modifications, and the adding of additional programs. We also want to be able to be clear about the need for scalability and address performance considerations as a part of that. And I think the other part of standardizing the business rules is so that it can be clearly communicated to participants, applicants in the programs about just what the eligibility rules are, and would also allow developers to more rapidly and efficiently develop systems.

Turn to page 11, further here on both page 11 and page 12, and I'm not going to read all these things to you, but there's a sense that we need to be able to work with existing state systems. We need to try to support and accelerate the state's ability to support the new business rules for ACA and the eligibility rules, once they've come out of CMS, that we need to create a buffer because there's going to be, in any of these kinds of systems, imperfect information and data, and there needs to be offline processes for being able to resolve those situations. We see this work really as an initial step. This is an incremental approach.

I think, if you turn to the next page, the consistent expressions also suggest to us that not only should it be incremental, but it should be ecumenical because there are going to be a variety of different systems out there. Some states will modify existing legacy systems. For the exchanges, we suspect there'll be the development of new systems. And we also expect that there will be a leveraging approach to potentially develop new Web front ends and interface them with existing legacy systems. Again, I'm moving fast, but that's an overview of where we are with business rules. This is probably the least developed of the four areas because we're still waiting for policy direction. As certainly you all know, technology can enable policy often, but we first need to be clear about what the policy is that we're trying to enable.

We'll move to the plan benefit handoff. The charge here was for the tiger team to identify the key data elements needed for data exchange between the health, the exchanges and the health plans, both Medicaid plans and commercial plans that data would be handed off to. We see this data exchange in a bidirectional manner with the exchanges, and we're trying to develop standards, where appropriate.

There are some key assumptions here that are worth mentioning. The handoffs would happen from the exchanges to the plans after eligibility has been determined. Again, this is the assumption that we're working under. The coverage periods, the effective dates would be contingent upon some policy decisions that have yet to be made and are not in our workgroups purview, but it seems to us that the consumer planned choice and the benefit choice would be transmitted in these handoffs from the exchange to the plan, and so the set of plan benefit handoff recommendations are on the next slide, slide 15.

And, largely, after looking at the individual data elements, there's a belief that existing HIPAA standards, 834, 270, 271 would provide the necessary framework to be able to do the handoffs. The standards handled all of the common identified data elements, including race and ethnicity, primary care providers handled by 834, and there's also a need, and it's highlighted in the ACA section, which authorizes this work to address transmission of eligibility determinations to consumers. We're expecting, in today's world, that much of that communication may happen via text, and it may happen via cell phone, and so we believe that the HIPAA transaction standard 271 could address this. That's where we are in terms of plan benefits, a third handoff, the third tiger team. Then the last tiger team charge is around privacy and

security, and their charge was to develop application of fair information practices, including the purpose and limitation of use and reuse of the data, and also to provide standards around security, safeguards, authentication, secure transport, audit logs, etc. What you will see, and I'm not going to read through all of these, is just the preliminary recommendations on where we are.

If you look at slide 17, you'll see that only the minimum data necessary for enrollment, eligibility determination would be collected. We're talking, again, about access to real time data and where data accuracy is important. We're exploring alternatives because a number of states do not require an SSN as an applicant enrollee identifier. We are trying to establish thresholds for levels of match using advanced probabilistic search to try to get a high degree of confidence in the match rate. And, I think, what's key here in the discussion we've had in this tiger team is to have clear, transparent policies about authorizing access, use of the data, and so on.

If you move to the next slide, it specifically addresses use limitations. We want to be clear about what the purpose is for which the information will be used and be able to clearly communicate that with the consumers. Largely now the three federal agencies that are providing some level of verification have data use agreements. We want to insure that those data use agreements are fully compliant. There is talk here also about not just putting the burden on the system do the verification, but we're trying to find these standards in such a way that it may also be possible, even though it may be more difficult, to have a consumer mediated model. We've heard some testimony about where that exists in the VA, this student aid, IRS connection that is in piloted, and we want to be able to support a framework anyway that could support either of these approaches, and I think we're moving in that direction.

Then on the last page, it's important—slide 19—for there to be individual control and participation, and this is particularly important when you think about individual circumstances changing and the need for an individual to be able to go in and update or correct information about their employment status, their income, and that we assume that the exchanges will be able to handle this type of a transaction model.

Sorry to run through this so quickly. I know I'm standing between you all and lunch, so let me turn it over to Doug, who is going to walk through the eligibility enrollment data harmonization project that he's directing that's now underway.

#### **Doug Fridsma - ONC**

Sure. Thanks, Sam. Just a couple of slides to kind of update you on what we're doing with regard to the data, the data elements and the service descriptions. This is really the first time that we've, in sort of a real world scenario, been using the SNI framework and the NIEM process to be able to get some sort of consensus around these data elements. Our objective was to inventory the core data elements that we have, so try to take a look at existing programs and existing data standards that are out there. Identify the commonalities among those data elements, and then trying to make sure that we are talking about the same thing when we're talking about exchanging information between these two different or across these different programs.

We took a look at six different health and human services programs: health insurance exchange, the Medicaid, CHIP, SNAP, TANF, and EITC, and used those basically as input. Try to figure out what kinds of data elements that those organizations use to be able to determine eligibility for different programs. And we initially started with a core set of data elements, approximately nine here that include date of birth, social security number, gender, income, citizenship, the legal status, address, incarceration, and household composition. Then we also took a look at some of the existing data element standards that were listed within the NIEM model, as well as HL-7 and some of the other standards organizations that were out there.

Basically the important thing to recognize is that if we want computers to be able to understand information and exchange it in useful ways, we have to first make sure that people understand that information and know how that gets exchanged in useful ways, and so that we need to make sure that when one agency talks about income, they're calculating it in the same way, or they think about it in the same way as another agency. Otherwise we end up having computers thinking that income is the same thing, but in fact, the people behind that have different definitions of what income is. And so our process has been to define first the scope. We've sort of talked about identifying the programs. We've taken a look at some sample states that have programs in place. And from that, we identified this core set of data elements.

The next step is to do some analysis on that, and that means to take a look at how the data is collected. What are the definitions that are used for the data? Identify the data in the analysis criteria, so if we talk about income or household composition, we need to know what do we mean. Is it gross income? Is it net income? Is it some other form of income that needs to be included or excluded from that calculation?

The same is true of households. Is it all the people living in the household? Is it people that you report on your tax forms? And so we've done sort of that analysis, and then once we've do that, then we take a look at all of that information, and we see where there are things that are the same, where there are things that are different. And then we can begin to harmonize those data definitions.

What's important there is that we don't need to come up with a single, unified view of the world, but what we do need to do is we need to have clarity so that we don't have people who are calling things that are different, you know, gross income and net income, and saying that's just income. We have to get clarity around the different data elements that are there and that when there are commonalities, when there is overlap, that then we agree on kind of what it is that we're going to use for that definition and that common data element.

And so we've taken a look at things like the data element name. For example, address would be an example of a data element that we've identified that's important. Within that, there are a series of sort of data element attributes or meta data or the like, so there could be sub-concepts of an address. There could be a home address and a mailing address. We have to make sure that we don't mix those up if we're trying to exchange information.

We have to make sure that we've got good definitions, so each of those different organizations may define things in slightly different ways, and it may seem a little obvious, but it's part of good discipline to be able to make sure that we document the definitions that people use for these concepts. Then, within that, the data element address may have a series of other components or attributes that would be in there, and so things like an address for a person may be broken down into a street address, a city, a state, and a zip, and maybe a four-digit extension. And for computers to be able to understand how to exchange that, we need to have that level of specificity and detail to be able to do that.

And so, what we've done is we've taken a look, and we're in the process, of course, of doing this analysis. But we've taken a look at some of the existing data models, including the data standards that are used for NIEM, some of the data standards that are used for HL-7, and trying to figure out if we can map common representation, so postal address maybe the equivalent of mail address, and location address and person address may be the same. But trying to get some clarity around that is part of this analysis.

We've also tried to take a look at this from the applicant's perspective because I think it's important for us, as we collect this data, that we do it in a way that doesn't get confusing and that is easy for the applicant to take a look at. And so we've been taking a look at how we might look at, say, household information and how we collect that information. And we've been fortunate to have a series of subject matter experts that are also taking a look at this and trying to take a look at some of the underlying business rules that are associated.

We're, right now, working on looking at things like derived data elements because if you collect their gross income and a series of other data elements, you can derive what their net income might be, and this is kind of what the IRS does. And so some of these elements are actually data that we take a series of data elements, aggregate them together, apply a business rule and can actually come up with some other information. But making that stuff explicit is what's important. We can't begin to even harmonize until we know what one group does versus the other group. You have to have that explicit ... first.

A whole list, this is a very busy slide, and I apologize for that, but I want to just sort of take you through some of our current assumptions and constraints, and then I'll turn it back over to Sam. Our current analysis includes the six health and human services programs and these nine core data elements. Some of those data elements, particularly things like income and household, we anticipate a great deal of variability and actually probably some additional attributes that need to be taken.

Our task is to try to standardize the data concepts and definitions, not necessarily the business rules, but throughout that we're really trying to make sure that we make everything explicit and that we don't have confusion when we use the term income as to what that means. We anticipate further harmonization of the income data element as the MAGI standards are published, and we plan to collect data details from a series of sampled state programs, recognizing that that may have a selection bias to some degree. We've looked at only those states that have currently used a portal approach to do this, but it's a good way for us to get started and kind of get our boots on the ground with all of this. And, wherever we can, I think we're going to try to leverage existing standards. I think we don't want to create new ones. We want to make sure that we just get clarity around the ones that exist.

One challenge is the limited information available regarding the earned income tax credit, but we're working through that. That is the program that probably has the least overlap with some of the other ones. But we're sort of working through that as well. And so, with that, I'll sort of end. I'm going to turn it back over to Sam to bring us on home.

#### **Sam Karp – California HealthCare Foundation – Chief Program Officer**

Good. Thanks, Doug. So you can see, this is quite a complex endeavor. As far as we know, this is an effort to look at these data elements and across systems, across programs, across the country hasn't been done before, but is critical, the work that Doug and his team are doing. Let me just do two final things. One is give you a sense about the kind of feedback that we've received and then talk to you a little bit about our next steps.

If you look at slide 25, we've had, I think, as of this morning, 43 responses to a blog that Aneesh and I initiated to try to generate some feedback. We've had an additional dozen or so responses via e-mail or letters. We've heard from 11 states. We've heard from consumers. We've heard from industry and associations. And just a few high level summary of what we heard.

We received a lot of support for the role that standards can play in simplification and particularly in use of multiple data entry points with 40 million newly eligible people for healthcare starting in 2014. This concept of a no wrong door, that you can apply online at home, in a library, wherever you have access to

a computer, apply at a clinic, a hospital, or a welfare office. Standardization of that application process would be critically important.

We've heard that people are seeing data standardization as a way of better supporting enrollment across programs. Many of the data elements, although not necessarily as Doug described, the definitions are the same in the Medicaid program, the food stamp program, the TANF program, and the standardization of the data elements across these programs might make it a lot more efficient for families to see if they're eligible using the same data set that they submitted once to see if they're eligible for other programs. There seems to be support for use of electronic verifications to help simplify this process, although we have received a lot of caution about the currency and completeness of that data and the need for clarity and disclosure about how that data would be used.

Then, lastly, there's been a tremendous amount, and maybe in a surprising way, encouragement for innovation in this space for use of the Web, for the use of shared business rules. There's not a lot of time between now and 2014 where states have got to basically modify existing systems or bring up new exchanges. There are not a lot of resources available to support states in doing that. So the more innovative use of technology, I think, is being understood as a real benefit here.

Just in terms of additional follow-up, Aneesh and I are planning to initiate another blog post and try to get some additional feedback, as we continue to refine the recommendations. We are going to conduct a couple of listening tours where we want to specifically try to get some input from state Medicaid directors and others at the state level. There's still an awful lot to do, and I hope you heard what we presented today as very preliminary, but we're making progress in literally the six weeks that we've been at work.

In terms of next steps, between now and the 11<sup>th</sup> of August when we're having our next in person meeting in Washington, our tiger teams working with staff are going to refine recommendations, address some of these gaps, and we hope that Doug and his team will complete the NIEM analysis. At this meeting on the 12<sup>th</sup>, we're going to discuss these refined recommendations, probably get some additional public testimony, and then hopefully by the middle of August to the early part of September, we're going to have a set of final recommendations that will be passed on to NIEM. That's our update, and I'm happy to take questions.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Richard?

**Rick Chapman – Kindred Healthcare – Chief Administrative Officer/CIO/EVP**

Yes. I appreciate the examples given about the problems and definition with determination of income, for example. It was an excellent example. I guess I just couldn't help but wonder, what are you planning to do or how are you going to approach this whole issue of citizenship and legal status?

**Doug Fridsma - ONC**

That was when we took a look at the citizenship and legal status, some of the programs had a binary construct where they said, are you a citizen or not, and so it was either a yes/no question. Others actually said what kind of relationship do you have? Are you a legal resident? Are you an alien? Do you have a green card? There's a whole series of other kind of value sets that they selected.

I think what we need to do whenever we take a look at these sorts of things is that it's possible using a business rule to say what is your current residency status and derive whether you are a citizen or not from that as opposed to just having a binary construct that says yes or no. So in nearly every situation, you know, the different systems will collect data. Conceptually that's the same, but they do it in a slightly

different way, and so that's part of this process is to get clarity around that so that we can exchange that information and apply the appropriate business rules.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

This is really excellent and challenging work. This reliable electronic verification will be a wonderful thing and would advance all of these programs. It has a lot of overlap with the work of unifying health records. In both cases, the risks are very high: whether it's financial or in the health record side, you know, mixing of the information that doesn't belong that has high consequences. Looking over your nine core elements or even the example sources you mentioned, can you give a concrete example of how you could, using those sources, either publicly available or private information that other people around you, close associates would also know or have access to? What's the scenario, an example for how you can reliably prove that somebody is who they are?

**Doug Fridsma - ONC**

How it's being done now, for example, in the CHIPRA program, and this is the testimony that we heard from Social Security Administration. There are data agreements between the children's health insurance programs in the states and SSA, which does all the things we would expect a data agreement to do, specify use, limitations of use, and so on. And they are sent overnight a list of applicants with core data elements, and I believe in that case they are only using four core data elements, and they do against citizenship records, which SSA has to do this match. We were surprised to hear that they had a 94% match rate, and they return, again, overnight, the results back to the state agencies. You know, this still leaves a number of kind of point-to-point verifications that need to be made, but we're led to believe anyway that while there are some challenges about completeness of data pre-1991 for example, that they have a process that they've been using now for the last, I think it's almost a year, that seems to be working pretty well.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Maybe I didn't state my question correctly. Perhaps I'm talking more about authentication, and it seems like if you're going to have the electronic enrollment online, you have to cover authentication as well. How do you do that with available, either public or even private data that is known by close associates?

**Paul Eggerman – eScription – CEO**

Paul Tang is raising an excellent question about patient authentication, but that's an issue that the enrollment workgroup is going to be working with, but also the privacy and security. We're actually going to try to do a common subgroup to identify that, but the basic concept there is if you do not have an identifier, a numeric identifier, what other data do you have? And can you match it up? If you can get an exact match on patient name and patient address that perhaps tells you something in terms of matching two different records together. What the group is going to be looking at is what are the criterias and what are the levels in which you would establish that kind of matching criteria because, in the absence of a patient identification system, you have to be able to use some of the other data elements to match.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

I think that's still talking about the linking problem versus the authentication problem. If someone is applying for eligibility or applying to look at somebody's record that's the counterpart, then what it is that you need to prove that you have the – you are an individual and have the authority to either apply or to look at a record? That's different from matching or linking.

**Paul Eggerman – eScription – CEO**

Right, and that also this group is going to have to address too. There are lots of ways to do it. If you look at NHIN Exchange, they have an approach where you actually physically have to appear and get some sort of a certificate, and so there's a number of choices there.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Yes. But they want ....

**Doug Fridsma - ONC**

Paul, you raise a really, I think, critical and important question, and that is, what you're really talking about is kind of identity proofing. When you go to, you know, when you fill out your passport application, somebody verifies that looks at your picture, and they look at your signature, and they look at your documents, and they translate you, sort of the carbon based life form into this piece of paper that serves as your surrogate that says you are who you say you are from this. The same thing happens when you get your drivers license and other kinds of things. A lot of times that happens in person. My bank does it. I go in there. I open an account. I have to do that in person, but then what they do when I sign online, they use two-factor authentication because they have my password, and then they send me a text message to my cell phone that I then have to enter as well.

I think there are two issues. I think there is an issue of identity proofing that we need to think about, and how do we translate essentially carbon-based life forms into the electronic certificates that represent them as they exchange information. I think the second piece to that is going to be the policy issue in the sense that we need to think. You know, we can do one-factor or two-factor or whatever kind of authentication is necessary, but that will come from a policy perspective that says, what is the strength of the identity proofing and authentication that we require for whatever use case or result?

I don't know. I don't think and, Sam, you can correct me. I don't think that within this group the notion of identity proofing has been addressed. I don't know if that's out of scope or if that's something that we just haven't ....

**Sam Karp – California HealthCare Foundation – Chief Program Officer**

It has not yet been addressed, and I know that our privacy and security workgroup was going to be talking with ONC staff. We didn't think we needed to create it on our own, but we hope to be able to leverage how it's being done other places and bring those back as models. But clearly, just as you said, we're looking for some policy direction.

**Doug Fridsma - ONC** I think the subtext of your comment, Paul, was that this group shouldn't do it by themselves, but in fact the issue that you've raised here spans across all of the kinds of exchange and authentication needs that we might have and that a common approach is probably a better way to do that.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

It's also saying that it is a problem that has to be solved to do NHIN Exchange.

**Doug Fridsma - ONC** That's right.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

On all sides, the patient, the provider, all the people who have to trust in the system have to be known and accountable.

**Doug Fridsma - ONC** I can give you an example just in terms of NHIN Exchange. You just mentioned that. Part of getting a certificate requires a notary, and you have to do it in person, and there's no way

around that. And so, people have sort of given some pushback and stuff. I mean, but it was one of those things that it was just part of taking that carbon based life form and kind of creating the electronic representation.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Gayle?

**Gayle Harrell – Florida – Former State Legislator**

I have to say, I get very nervous on these conversations. I just see the big database in the sky, and it opens up huge privacy security risks. I get extremely anxious about the potential misuse of something of this, especially without that identity proofing. It makes me extremely nervous, and I think we have to be very cautious how we go down this road.

The identity proofing, I'm so glad you brought that up, Paul, because I think you have got to know who is who. You have to verify, whether it's verification, very specific verification of citizenship for eligibility. You also have many different requirements in states as far as Medicaid eligibility. It's very different in New York, say it is from Florida, so there are many, many problems involved in this. I just have a real warning signal going off for me that we have to be very cautious how we do this.

**Doug Fridsma - ONC** We're going to take that caution back to the committee, and we certainly share it.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Any other questions or comments? Charles?

**Charles Kennedy – WellPoint – VP for Health IT**

This is a question of scope. The project you presented seems very appropriate, but it would be what we would call a back office project, you know, how do you move data, how do you make the enrollment process work. But in enrolling people in the health plans, there's a front office process. How do you engage the individual so that they're empowered with data and decisions to make the appropriate decision that's best for them, and I'm just wondering? Is that completely out of scope for what you're doing, or is that being addressed in any way?

**Doug Fridsma - ONC**

It is out of scope for what we're doing, Charles.

**Charles Kennedy – WellPoint – VP for Health IT**

Thanks.

**Doug Fridsma - ONC** We'd like to help you out, but—

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

That's in the next release. Any other comments or questions?

**M**

Thank God it's out of scope.

**Art Davidson - Public Health Informatics at Denver Public Health – Director**

You have on this last slide that's up there now, voices from consumers, industry, and associations. I just wonder if there had been any comments from the HIEs or the RECs so far.

**Doug Fridsma - ONC** I've read through all the blog comments. There have not.

**Art Davidson - Public Health Informatics at Denver Public Health – Director**

Do you think that that's something that is required, as you try to move this forward, get their ideas early on?

**Doug Fridsma - ONC** I think it could be helpful, and I'll take back the suggestion that we reach out to them. Just being involved here in the HIE in California, I know they're struggling with just organizational issues and focusing on their own set of directions, but it certainly doesn't hurt to reach out to them.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Any more questions, comments? Miraculously, we're precisely on time. Thank you very much, Doug and Sam. We'll adjourn for lunch and resume at 12:45. Thanks.

(Break)

**Judy Sparrow – Office of the National Coordinator – Executive Director**

I think we're ready to begin, Dr. Tang.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Thank you. Good afternoon. Welcome back to the HIT Policy Committee meeting. The second moment we've been waiting to here is the one for the privacy and security tiger team that we heard about meaningful use this morning, and we also heard, as part of that discussion, how core and central privacy and security is as a foundational requirement. You all know that there's been a tiger team, I think, because they meet every couple weeks to hammer out – that must have been a joke. Every couple of days?

**W**

(Inaudible.)

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

I did call the pace astounding. To hammer out some of the guidance and issues because so many people are depending on it, whether it's the HIE groups, the state designated entities and the states working on these, the HIE, health information exchange in the states, or just needing to move information around in ways that HIPAA never dreamed of. We need to work on this problem.

Heading up this tiger team, I called it cheetah last time, and I think that was well deserved, are Deven and Paul, and so they're going to report on their work and going to ask for a series of acceptance or approval of the direction they're going because this goes in stages. It'll evolve over time, and I think their plan is to bring back and entire package to us. But in order to make step-by-step progress and to move forward, I think they would appreciate, one, the input and discussion by this group, but, two, an ability to move forward and put some of these assumptions in the accepted or approved state as they go forward. Deven and Paul?

**Deven McGraw - Center for Democracy & Technology – Director**

Just to start with, this slide reminds folks about what our charge is to address privacy and security issues raised by ONC, provide some practical guidance on health information exchange, try to evaluate these difficult topics within a specified context, try to reach consensus in developing policy recommendations at an appropriate policy level versus down in the weeds and then, of course, to document decisions and conclusions. Here is a list of the members. It's a number of folks from our policy committee, as well as a

number from the standards committee, and also representatives from the NCVHS privacy and security workgroup.

I just want to say, Joy mentioned it earlier, every two-week meeting, ha-ha. We scoff at that. Our meetings are twice a week for three hours at a pop typically, so it's very intense, and so I think it's worth mentioning only because the people who have agreed to this rigorous schedule need to be thanked for their time and dedication.

Just to give a summary of where we're headed here, we have two groupings of recommendations. The first set, which I'll present, are on fair information practices and health information exchange, focusing in particular on collection use and disclosure limits, including data reuse and retention. And then Paul will pick up with some general level recommendations on consent, so that's a yes/no level with some later discussion about into some of the more granular components such as based on type of data.

I also want to sort of level set the discussion here that we looked at health information exchange in the context of the exchange that would be required for purposes of stage one meaningful use. It says proposed here, but it's actually now that we know in fact what stage one meaningful use is going to be, there isn't really a deviation from this slide. It's those elements in the dark blue or purple bubbles up there with sort of numerous other aspects of information exchange, including exchange with patients, making data accessible for research purposes, as well as for payment. Certainly it's not as though we're not – we realize that those are envisioned as part of health information exchange going forward, but if there's one thing that we've learned in doing all of this is that focusing and trying to narrow the scope in taking this one step at a time is absolutely essential to being able to make progress.

Therefore, we really did try to focus on the type of exchange that's required for meaningful use. We intend to take up these other elements down the road. Again, the idea is to come up with a package of privacy and security recommendations that really span the landscape, but have to start somewhere, and this is where we started.

Again, beginning with recommendations for fair information practices and health information exchange, so here are our fundamental overarching policy recommendations to present to you. It starts with the relationship between the patient and his or her healthcare provider, and that is really the foundation for trust in health information exchange. And so we have two corollary points to that that were actually part of the recommendations that Paul presented to you at the June meeting, and that is, providers really hold the trust then and are ultimately responsible for maintaining the privacy and security of their patients' records. But we recognize that in the world of HIE where there are lots of functions and activities that providers may need some assistance, that they may delegate certain decisions related to exchange to others if the delegation is done in a way that maintains that trust. That's really the core or the foundation.

Again, given that we envision and accept that providers are not going to do this alone. And, in fact in many circumstances, they will hire third party service providers or intermediaries. HIOs would be one example of that. But there's a multiplicity of entities that are going to be involved in health information exchange, and it's critical that all of the entities that are involved in exchange follow the full complement of fair information practices when they are handling patient information.

What are these fair information practices? They include transparency, data integrity and quality, purpose specification, collection, and use limitations, data minimization, security safeguards, individual access and control, and oversight and accountability. And if you want to know where these have been articulated, in fact, the Office of the National Coordinator has them in the nationwide framework for health information exchange, which we incorporated specifically into the strategic framework document that we spent many

months discussing not very long ago, so this should not be new, but we want to put before you this, we think, very important first principle that in fact all entities involved in exchange need to follow, again, this full complement of fair information practices.

Then what we did was to use these principles and particularly those related to purpose specification, collection, and use limitations and data minimization, which there are some definitions in the slide that I'll talk about in a second to answer some very specific questions on exchange so that it's very clear what we mean when we say that fair information practices need to be adopted by all entities involved in exchange. And so what we mean by purpose specification is that in fact the purposes for which personal data are acquired, exchanged, retained, and are used are actually expressly stated. That information is only acquired by fair and lawful means, and entities involved in exchange acquire, exchange, retain, and use only the information that's necessarily in fact to fulfill the purposes that are specified. And use limitation means that personal data should not be disclosed, exchanged, retained, made available, or otherwise used for purposes other than those specified. They seem like very common sense concepts, but they have important implications for how, again, both providers, as well as these third party entities that will inevitably need to be involved in facilitating health information exchange, spelling out their obligations with respect to information.

The specific questions that we addressed include the following. Should exchange of IIHI, which for those of you who are not familiar with the acronym is individually identifiable health information. It's a broader category of personal health information than just PHI, which is a term of art called protected health information. It has a slightly more narrow context, and we wanted to be clear that if it's identifiable information, it's IIHI and not the slightly smaller subset called PHI.

Should exchange of that for treatment purposes be limited just to the treatment of the individual who is the subject of the health information and not necessarily other patients? This is for those of you who know HIPAA know that in fact treatment under the HIPAA definition includes treatment of the individual who is the subject of the information, as well as treatment of others. And so we wanted to get some clarity there.

In order to facilitate a request for individually identifiable health information, how should the relationship between the provider and the patient be confirmed? Will providers who are not covered by HIPAA be permitted to access identifiable health information through an HIO? That's the noun form, HIO. If so, what if any additional requirements should be placed on these providers, and should data exchange with non-HIPAA covered entities be permitted? How should public health reporting be handled? Again, sort of sticking to those pieces of exchange that are covered in stage one of meaningful use. How should quality reporting be handled, and what limits, if any, should apply to third party service providers regarding data reuse? And what limits, if any, should be applied to retention periods?

Now we actually have some answers drafted up to these questions, and they can be found in the— Paul's reminding me there are two more. See, we have been really busy. Thank you. The two additional questions: should third party service providers disclose to their customers, which is primary, the providers who hire them to perform a service or function? How they use and disclose information and how their privacy and security and retention and what their privacy and security and retention policies and procedures are, I think we – in terms of whether those should be required to be disclosed. I want you to note that here we don't use the acronym IIHI. We're talking about information generally, and so that, as you'll see in our draft answers, would include how they use de-identified data.

And the last question is whether business associate agreements are sufficient for insuring accountability. This question was specifically raised in the context of some recent changes to the HIPAA privacy and

security rules that were proposed by the Office of Civil Rights within the Department of Health and Human Services that clarify, first off, that subcontractors to business associates under HIPAA are themselves business associates and, therefore, held accountable to the terms of their business associate agreement, as well as the need to comply directly with privacy and security rules under HIPAA, and so we had an answer to that question as well.

Now we'll get to the part that I skipped to, which is that we actually have some answers that we've proposed for each one of these questions. Given that we don't have as much time with you today as I'm sure you would all have liked, we've put these answers in the appendix and hope that you have had a chance to read them. Again, because the recommendations that Paul has to present on the issue of consent are important, and we want to have a sufficient amount of time to discuss all of these, we are not going to go through in this verbal presentation all of the answers. But I want to highlight and hopefully I can do this without completely mucking up the slides.

Yes, I want to talk in particular about the recommendations on data limitations for third party service providers because I know that was a topic of some discussion at the last policy committee meeting, and so as you go to this question, again, of what limits, if any, should apply to third party service providers regarding data reuse, we say very clearly that the principles of collection limitation, purpose specification, and use limitation should apply to provider and third party service provider uses of identifiable health information, and that a third party service provider may not retain, use, and disclose for any purpose other than to provide the services specified in the business associate or service agreement that they have with the data holder, the data provider, and any supporting administrative functions that are needed to be performed in order to facilitate that arrangement or, of course, if they are required to disclose something by law.

Similarly, what limits, if any, should be applied to retention periods? Here again, applying the overarching recommendations of requiring these entities to comply with fair information practices, we said that in this context, they should retain data only for as long as reasonably necessary to perform the functions that are specified in their business associate or service agreement with data providers and the supporting administrative functions that allow them to carry out those responsibilities, and they should establish retention policies. They should disclose them to the entities with which they contract. At the end of the retention period, that data should either be securely returned or destroyed per the NIST standards that apply, and to the breach notification safe harbor, for those of you who are familiar with it, and all of that needs to be set forth in the business associate or service agreement. Similarly, on the issue of disclosure about how they use and disclose information to their customers, they should in fact be obligated to disclose in their agreements with customers how they use and disclose information, including, without limitation, the use and disclosure of de-identified data and their retention policies or procedures. So this is clearly on the transparency point of fair information practices, as well as those of collection use limitations.

Then finally, on the question about whether business associate agreements are sufficient for insuring accountability, we recognize that the proposed privacy and security rules on business associates and subcontractors have made significant strides, but we don't think that by themselves they're going to be sufficient to address the full complement of governance issues, including oversight, accountability, and enforcement, which just once again tees up the governance question, Jim, that you teed up earlier today and one that is on our agenda to provide some recommendations on later this summer. And so I'll see if Paul has anything to add and turn over the slides to him.

**Paul Eggerman – eScripton – CEO**

Great. Thank you very much, Deven. That's a lot of material, and you can see we have been very busy doing a lot of things. Let me see how I get the slides back to where we're supposed to be.

**Deven McGraw - Center for Democracy & Technology – Director**

... sorry.

**Paul Eggerman – eScription – CEO**

That's okay. Deven has done a great job of presenting the information about fair information practices and, from there, we moved on to a discussion about consent, which is a challenging and contentious topic. This is a very interesting topic, and to explain how we did this, in doing this, we first assumed that all the participants. We first assumed that what we already had discussed about fair information practices would be accepted, and that participants would all go by that. We assume that everybody is going to follow the law. We also assumed that whatever constraints, security rules that we placed on all the participants, that everyone would do those also, so it was sort of like everyone is playing by the rules. Those were some assumptions that we made.

Then we started this discussion with the same fundamental principles that Deven referenced for fair information practices, which I also referenced last month when I talked about the message transport, which was we looked at the patient/provider relationship. We said that that's where the trust is held. It's the foundation of trust. We said health information exchange was the foundation of trust basically for everything in healthcare. We said that's basically our starting point. In that, we said providers hold the trust, and ultimately they are responsible for maintaining privacy and security of their records, but under some circumstances they can delegate some aspects of that. That's one sort of foundational principle we used.

We used a second one about considering patient expectations, which we summarized this way. Patients should not be surprised to learn what happens to their data or learn what happens to their medical record. This should not be a surprise. We used those two principles to make our decisions about consent or choice.

In framing this discussion though, we want to be very clear that we are reviewing consent from the standpoint of a patient's participation exchange generally, which is like yes or no. We are not yet discussing more granular issues based on the type of information, which we will be doing at— Actually, we're going to hopefully start on Friday, but we will be presenting to you hopefully in August. This deals with what NCVHS is defining as sensitive data. Some people say everything in their record is sensitive, but there are some particular areas, so we're not dealing with that. We're only dealing with the more general issues. By dealing with it on a yes/no basis, we're also implicitly asking a question that sometimes gets asked, which is, is participation in these exchanges mandatory? And so we are clearly saying no, it's not mandatory, that patients can decide whether or not to participate, and so we're framing this discussion as a discussion between the patient and the provider, which is sort of like the starting point before any data is sent to the exchange. That's part of the framing part.

I also want to remind the policy committee of the previous privacy and security workgroup recommendation that was approved by this privacy committee, which is that no additional patient choice is needed beyond what current law requires in directed exchange from one provider to another for treatment. This is like a physician orders a laboratory test or a physician gets a radiology interpretation coming back from the radiologist. It's not a consent issue. Or if a primary care provider sends a patient to a specialist. When they send the patient to the specialist, they presumably do some sort of referral, but they need to tell the specialist whatever information the specialist needs to perform whatever the specialist is supposed to do. In those situations, actually, instead of being surprised, the patients are

annoyed if the other party doesn't have the information they need. Those cases, those do not require consent.

The question is what does require consent? That's what we answered. We had these six questions, the first three of which we're here to tell you the answer to, what factors or the way we tried to answer it. What factors trigger the need for consent to participate in information exchange? The second one is what approach should ONC take to a national policy on change? And the third one—

**Deven McGraw - Center for Democracy & Technology – Director**

Choice.

**Paul Egerman – eScription – CEO**

Sorry, on choice. And the third on—thank you—the third one is what about the providers. Should providers have a choice as to whether they participate in models of exchange? The other thing that are sort of grayed out are issues that we will be addressing later about education and management and durability of consent.

The first one, that's a key issue is what factors trigger the need by a provider to obtain the patient's consent. Again, this is consent between the patient and provider. And on the screen, there are a lot of words. And so to try to make this a little bit simpler and clearer from all of these words that are on this screen is that I would just return to the original, the previous slides about the patient/provider relationship.

You have this concept of trust, and basically the information is held within that patient/provider relationship. And what we're saying is, well, you need to have a sense of consent if the patient's provider no longer has control of the patient's medical record data. If that control somehow goes to some third party service organization, some HIO, if they get control of the record, then that's an issue of consent. The second issue there that's also really important is related to the first one. If the patient's health information is retained for future use by a third party, and this is when we talk about third party or intermediaries, but usually that means HIOs. And so we listed out six issues here.

The third issue relates to if the HIO or third party gains access to the patient's health information, which might be an issue that some people might want to push back on a little bit based on last month's discussion. Then we have an issue of aggregation if the data is aggregated from multiple medical record sources, and the aggregation is occurring not by provider, but by one of these third party entities, and then also the issue of sensitive information, again, sensitive as defined by NCVHS. The existence of sensitive data also could be a trigger for consent. And the final issue is if any of the other things change in any point in time, then that also triggers consent.

This is a very interesting and important discussion, and these are the triggers that we laid out for consent, again, generally for the more complicated or for areas other than directed exchange, generally for more complicated models of exchange. So from there, we went on to the very exciting issue of what form does this consent take. The first concept we have here is simply to say choice should be required if any of the factors in the previous slide are present. That means any one of those factors. And ONC should promote this policy through all of its policy levers. This is another way of saying this is critically important, and there are multiple policy levers, and ONC needs to use all of them.

From there, we defined the choice itself, and we produced this list, which is a set of policy guidelines in effect as to what this choice should look like. This is a really great list, but I want to make sure I credit the Markle Foundation where most of this list came from that helped us produce this list, some of their work. But the things we're saying about this consent, this decision is, first, the patient must have advanced

knowledge in time to make the decision. And we have a whole series of things listed after that. They have to have the ability to make the decision outside of an urgent need. It can't be compelled or used for discriminatory purposes. Full transparency and education is required.

Things like the fifth one down is very important. Choices need to be proportional or commensurate with the exchange circumstances. In other words, you have to know something about the exchange to understand what the best approach to the choice is.

Then, finally, consistent with patient expectations for privacy, health, and safety, and address the break the glass scenarios, so this slide is very important. This is like the basic policy guidelines for what should happen with consent. Having gone through the guidelines, as we had our meeting, I made the decision of saying, okay, what does this mean? Does this mean opt in or opt out? As you can guess, that's sort of one of these questions and issues like, you have to fasten your seatbelt for the discussion because the people have some very, very strong issues. We had a spirited discussion on this topic, is what I would simply tell you, followed by, I would say, 200 to 300 e-mails.

**Deven McGraw - Center for Democracy & Technology – Director**

I don't think it was that many, but it was a lot.

**Paul Eggerman – eScription – CEO**

There were a lot, but it was also a very good discussion, but this is a very important issue, and so what we came here was actually we came up with two views. And so the two views, and there's some more detail in the appendix of these two views. The first one is that the form of choice should be based upon the meaningful choice rules and left the decisions to be made by providers and patients and HIOs. That's one view. The other view that was presented was other members of the team felt very strongly that from the issues listed on question number one, in other words, the trigger questions, opt in should be required. The people who believe that believe that with a great deal of passion, is what I would say, and so those were the two approaches.

Now as we continue to discuss these issues, what happened was between these two choices, at least through the e-mails, what happened is a lot of people who favored the first one were starting to say, well, yes, a lot of situations opt in does seem right. Certainly when you look at the meaningful choice rules where you have to give advanced notice, opt in seems right, so there was a little bit of motion. It's hard for me to tell you when we start the discussion. The first one was the majority view. The second one was the minority view, but it's hard for me to tell you where that is right now. I think there's been some amount of progress.

To give you my own view of this issue, my own view is when you look at this issue, the end result is the same no matter what you do. The end result is the patient data is not sent to the exchange. That's the end result. To me, that's the most important part of the discussion is what are the things that trigger that end result. And this other part is actually an issue, in my opinion, of form over substance. And so the issue that people say about whether it's opt in or opt out, the people who are reluctant to say opt in for every circumstance, the reasons they're reluctant, they say, well, we need to know what the circumstances are in the exchange, and they don't want to create like an administrative burden where if 98% of the people are already saying yes to this thing, why do you make 98% of the people sign a form for the small percentage that are going to say no? Maybe that's not the most efficient way of doing it, and it comes back to some of the things we did in the early days of the HIPAA privacy rule where everybody had to sign a form, and that was just, like, annoying to patients. Not only annoying, but it created a management challenge.

Those are some of the arguments for the first approach. Again, the first approach is people are afraid that if we put up too many barriers, patients won't sign up for something that could benefit them. Those are the arguments for the first approach.

For the second approach the arguments are, again, very passionate. People have to have notice. They have to know what's going on.

Where we're going to take this discussion is we're trying to see if we can carve out from the first question perhaps a set of circumstances that we can get agreement on as to that that's where opt in would make sense to at least have an example for ONC, but we think we've taken this discussion pretty far already for ONC by providing these two alternatives because we are providing two very clear alternatives, and the meaningful choice rules, we think, are very good.

The next question we addressed was this one. Should providers have a choice about participating in exchange models? In this page, we don't have a lot of words on the page. We have a simple answer. The answer was yes because the way we looked at this is they already have a choice. If the providers want to, they could keep the records on paper, so that's one way they cannot participate in the exchange, so we have to give them a choice.

Ultimately, when you look at the total of what we're saying about consent, we're talking about a voluntary process where there's opportunities for patients to say they don't want to participate, and opportunities for providers that don't want to participate. And so that we think it's important because we're saying ultimately to be successful, we're really talking about health information exchange, but this is probably true for everything we're doing with electronic health records is we need to earn the trust of both the consumers and physicians. We need to earn their trust. We need to get people comfortable that this is all occurring correctly, and that's the process.

We've made these various recommendations. I want to explain what we'd like to do with these recommendations. We're asking you to accept our recommendations. We're also asking you for whatever feedback you can give us on these issues, especially on the consent issue that that would be most helpful. But the reason we're asking you to accept these is we're going to be coming back hopefully in another month with another series of these, and then when we get all done, I suspect in September, we're going to come back with a complete package and a single document.

When we do that, there'll be another opportunity to review the whole thing as a whole, but it's really important that we sort of keep moving forward and accept what we've done going forward. But when we review it as a whole, we may discover there's something we did that we learned when we talked about sensitive data that changes some of the, for example, a data collection decision that we made. But anyway, that's the discussion about consent, and before we open up for questions, we have a few workgroup members here. I don't know if you want to say anything, Judy?

**Deven McGraw - Center for Democracy & Technology – Director**

Yes. I'd actually like to comment for a second on the consent pieces. Just so it's clear to folks that the factors that we came up with to trigger the need to obtain consent for the patient's information to be part of health information exchange, we did this. Again, we didn't pull these out of the air, not suggesting that you would think that, but the fundamental principles that came before this of the patient/provider relationship is the trust foundation for health information exchange and that patients shouldn't be surprised by what happens to their data. Motivated us to think about the types of arrangements where there would be a deviation from that typical model of how health information is held and moved throughout the system that would say, well, it's not that we're saying that none of these things could

happen. But patients ought to have some right of choice about whether their data is part of it. So just, again, to understand where these came from, I just wanted to underscore that.

**Paul Eggerman – eScription – CEO**

Did you want to say something Judy?

**Judy Faulkner – Epic Systems – Founder**

Yes. First is just to ask you a question because I'm a little confused still about patient choice and opt in and opt out. I want to give an example with direct exchange. A patient normally goes and sees several physicians at provider healthcare organization A. The patient is in another city or even in the same city, has an accident, has a problem, goes to the ED at provider organization B that does not have the patient's records. B's computer pings A. A's computer recognizes B as a provider, recognizes that that patient has been admitted or is in the ED or is a scheduled patient, so it's a legitimate patient, a legitimate provider, and ships the things over. Does that require opt in or opt out?

**Paul Eggerman – eScription – CEO**

No, it doesn't require any choice. That's directed exchange. It does not require ... it's also probably a break the glass scenario too if it's an ED situation.

**Judy Faulkner – Epic Systems – Founder**

Or maybe it's not an ED situation, but yes.

**Paul Eggerman – eScription – CEO**

But even in that example, that does not require it.

**Judy Faulkner – Epic Systems – Founder**

Okay.

**Deven McGraw - Center for Democracy & Technology – Director**

It doesn't trigger any of those factors in my view.

**M**

Why doesn't it trigger number one?

**M**

Yes.

**Deven McGraw - Center for Democracy & Technology – Director**

Because the provider was pinged and released the data, so that data is still in the control of the provider who ....

**M**

No, it is not. It's not. I mean, it's not in my control. The patient signed consent in my office or has come to see me, but now the data is somewhere else. It's in an emergency room somewhere, and it's out of my control. It's in the hands of another provider.

**Deven McGraw - Center for Democracy & Technology – Director**

No, the control decision about when it's sent, when the information is sent. Yes, after you send it, it's in their control, but they didn't have it to begin with. And where the decision was made to disclose it was still with the provider who held the record.

**Paul Eggerman – eScription – CEO**

Yes. In other words, you're still controlling the access, and you give the access to the ED. In the example that Judy gave, it would be no different than a current situation where somebody at the emergency department picked up the telephone and called the provider and asked for information. The provider would say, oh, you're from this emergency room, and it would give the information.

**M**

It's in the hands of the ED. It's out of my control, and the patient has not signed consent.

**Deven McGraw - Center for Democracy & Technology – Director**

Again, so perhaps we should clarify. This factor is especially the one is about the decision to disclose. Is it in your control? We can make that more clear, but I think that's what we intended there.

**M**

Yes, that's not clear at all.

**Paul Eggerman – eScription – CEO**

That's correct, it's the decision to disclose.

**Deven McGraw - Center for Democracy & Technology – Director**

Right, not after it's disclosed. Of course it's not in your control anymore. Somebody else has it. But that was intended. The only reason why that happened is because you made the decision to disclose it.

**M**

The provider did.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes, the provider did. That's right. That's right.

**Judy Faulkner – Epic Systems – Founder**

The other thing I wanted to say is I think that we're getting into very morally and ethically complex issues. There is not a clear answer, and we have to make complicated decisions, and very important decisions, as I think I've said before. My husband is a pediatrician, and one of the children he cared for went to the "wrong ED", and died because he didn't have her record. And that's a problem that lasts, but that's anecdotal. And when I look at the opt in write up that we got, to me that's anecdotal too. And we have to be very careful of hearing vocal people say I do or don't want my record, whatever is done with it. And, instead, I think we have to be data driven, and how do we get the data then to make the right answers rather than anecdotal information. Evidence-based is the way, I think, as a country, we need to go, and I know I've been misled personally by vocal minorities, and we have to look deeper than that.

The other thing that I think of, as we talk about this stuff, and I think I, again, am responding to that document that we all got is that those who are vocal are going to be the most able then to opt out because they are concerned. I'm more worried about the 20-year-old who thinks that he or she is immortal and that patients who don't have enough time to go opt themselves in or the patients don't have enough time to opt their kids in, that they're the ones who are, in the end, going to end up in great health danger. Because the ones who want to opt out are so vocal, that gives them the ability. We get the ability to do both: allow the people who might otherwise miss it to get their healthcare cared for, and allow the very concerned people who are going to pay attention to this to opt out.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Neil?

**Neil Calman - Institute for Family Health - President & Cofounder**

It's up to Paul because....

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

We'll just go to a discussion.

**Neil Calman - Institute for Family Health - President & Cofounder**

First of all, I just want to say that I'm a retired member of the workgroup. I retired because anybody that thinks they can put six hours a week into this, it's just unbelievable what you guys have done, so it's just amazing, and I applaud you because I was unable to maintain that level of commitment. But that won't keep me from making some remarks now.

**Paul Eggerman - eScription - CEO**

We miss you.

**Neil Calman - Institute for Family Health - President & Cofounder**

The two that I want to make are this. We have to pay attention to the administrative burden on providers. Things are just getting worse and worse by the day, and every minute of a provider's time that's taken up in non-healthcare provision of service is especially looking at the number of people who are going to be driven into access to healthcare over the coming years and the shortage of specifically primary care providers, but providers in other fields. If we don't pay attention to that, this is one of those things where we'll do something perfectly on the side of getting all of the paperwork done and will be losing something tremendous on the side of the volume of patients and things that people are going to need to see. And so I think that we really have to pay attention to this.

I don't think opt in is a reality. It's not a reality for a couple of reasons. One of them is, I have 100,000 patients in our network. How am I ever going to get them to opt in? How many years is it going to take for me to get them to a point where every time they come in, we're going to have some mechanism of getting them the time for somebody to sit down and explain to them what all the implications are and all of the people that might have access to their data, and all of the intricacies of this, which, you know, from my perspective, I barely understand, but to be able to actually do what one would consider informed consent is going to be incredibly time consuming. And I haven't seen anything on the part of ONC that really yet has said that the government is going to take on the burden of informing people about all of these things that we're doing. And I think that's critically important. I don't think we, as individual providers, can take on the burden of talking to people about these processes for the first time. This has to be a function that takes place at a different level because it's just not going to happen. So opt in just isn't real because if we want this thing to take off, and we want people to be able to ping systems and actually get data, it's going to take years until people make appropriate connections with the healthcare system in a way that somebody can actually sit down and consent them in an appropriate way.

What's going to really happen is we're going to generate millions of pages of paper, and people are going to be handed things with lots of small print like with the privacy notices, and they're going to sign off on them in a split second while somebody is shuffling them into an exam room. The reality of it is there will be no useful information that's really passed through this, and it will be an enormous administrative burden that's not going to have any real value. And I think that's the reality of what happens a lot with the privacy notices. Many people have gone to doctors. I don't think anybody can tell you what those notices actually say, and that we've probably signed them a dozen times.

I really believe that it's got to be an opt out process. Having said that, I will tell you, I'm prepared in our system. And I don't know if this is legal, but I just thought of it as you guys were presenting, to basically tell people that come to our practices that this is what we do, and their way to opt out is not to come to one of our practices. We do that already in a lot of different ways. If somebody wants to see a neurologist, we don't have neurologists in our practice, and if they believe they need to see one, they go someplace else.

I'm prepared in an electronic environment to say this is the way we do business. This is the way we communicate with our colleagues. This is the way that we guarantee that we can provide a certain level of service, and I appreciate the fact that you may not want to be part of that process. But if you don't want to be part of that process, you can't get care in one of our centers because that's the way we do business, and I don't know if we can do business in two different ways in an electronic environment and in a paper environment where things get passed and Xeroxed and whatever else we do in a different way. I don't think that's a reality of the way people do business anymore, so those are just two fairly strong comments.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Fairly.

**Paul Eggerman – eScription – CEO**

We missed you, Neil.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

I need to give Gayle equal time. Gayle and then Christine and Adam.

**Gayle Harrell – Florida – Former State Legislator**

Yes. Being the author of that document that you got on your plates, I would like to defend it. I truly believe we have a constitutional right to privacy in this country. The last I read, the ONC hasn't rewritten the constitution, nor has the committee. I think we have a very distinct right to privacy that is not only guaranteed in our constitution, but also has been upheld vigorously in our courts. I think, speaking to people across the country and across the state of Florida, I believe that people understand that, and there is nothing more private than your health information. Once your health information has been, very private health information has been divulged, there's no way to retrieve it. You can retrieve your financial data. You can be made whole in a financial aspect, but there's no way that an individual can be made whole if very personal, sensitive, private health information has been divulged.

I think we have a responsibility to protect that. We have a constitution. People have a constitutional right to that. And I think we need to, in our policy decisions and our recommendations to the ONC, we need to make it very clear. There are scenarios, you know, ER, ED scenarios where, yes, you may have to break the glass, and we need to make sure that we have those options available in those pediatric situations, in accident situations or whatever. And there have to be some safeguards there, but I think when it comes down to it, we have got to make sure that there is real choice for patients with what happens to their private information. And we should not let a system determine how we do this. The architecture HIO or whatever should not be making these policy decisions.

I think we need to give some direction. I think there needs to be full public debate on an issue such as this. I would encourage states to do likewise. Ultimately, a lot of states will do that through their state legislatures. But I think there are lots of policy levers that we have through the ONC and through the HITECH provisions of ARRA to really give people the choice. Opt out is really not a choice. It's by

delaying that, by forcing people to, after the fact, opt out, that is not choice. And I think the only real option methodology that gives choice is opt in.

I really, you know, as Paul says, we've had very passionate discussions on this, and I invite you to really read that document. Take it to heart because I think there are many people in this country who will opt out. I think we need to, if we do not allow this to really, really involve the individual patient in making that choice. I think it's a right they have to do.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Christine?

**Christine Bechtel - National Partnership for Women & Families – VP**

... on that ... for me. Let me start with the easy point, which is, Neil, to your point. I think you're absolutely right about education, and I would just remind us that ARRA actually established a consumer education campaign specifically about the use of electronic health information and privacy, so I know that ONC is doing a lot of work on that, and I think it would be very appropriate at the next policy committee meeting to get a detailed update on exactly what's happening.

Let me just say that I want to ask some questions because I think I'm a little bit alarmed by what I'm hearing ... as sort of a global discussion opt in, opt out. I think it's absolutely not helpful, and I'm not sure. Coming in today, I understood. I thought I understood what we were talking about, and now I'm not sure I do, so let me just ask a couple questions. When we say we have two bullets on slide 22, and the second one is opt in, now that is not opt in to health information exchange RHIT large, or to the fact that my data is kept in an EHR, right? That is opt in when those factors on slide 19 are present. Is that correct?

**Paul Eggerman – eScription – CEO**

That's right.

**Christine Bechtel - National Partnership for Women & Families – VP**

Okay. So that takes me to the first bullet, which is, I'm not sure what the options are in sort of a modified opt in because it feels to me now like basically the same thing where we're saying anybody, you know, if any of the factors on slide 19 are present, then what are the forms of choice here that we're talking about?

**Paul Eggerman – eScription – CEO**

There would be a choice that does what shows on 21. In other words—

**Christine Bechtel - National Partnership for Women & Families – VP**

On 21?

**Paul Eggerman – eScription – CEO**

On slide 21. In other words, what the alternative to opt in people are saying is, well, you have the guidelines for meaningful choice, and the provider simply has a responsibility to make sure that they meet those guidelines.

**Deven McGraw - Center for Democracy & Technology – Director**

Actually, I disagree. Those guidelines apply whether it's opt in or opt out.

**Christine Bechtel - National Partnership for Women & Families – VP**

Absolutely.

**Deven McGraw - Center for Democracy & Technology – Director**

Opt in, it's a temporal consideration.

**Christine Bechtel - National Partnership for Women & Families – VP**

Right.

**Deven McGraw - Center for Democracy & Technology – Director**

Is the choice before or it is a choice to have it pulled out after the fact?

**Christine Bechtel - National Partnership for Women & Families – VP**

Right.

**Deven McGraw - Center for Democracy & Technology – Director**

And you could actually even structure an opt out with a time before, but the default would be that you're in unless you opt out. So maybe it's temporal is not the way to describe it. It's what's the default mechanism if the patient says absolutely nothing, but all of the elements of meaningful choice we thought, as the tiger team, needed to apply regardless of when that choice took place.

**Christine Bechtel - National Partnership for Women & Families – VP**

Yes, and I could not agree with that more. I think that the piece that is maybe applicable, I think, Paul, in what you're saying is the fifth bullet on that slide, which is choices proportional or commensurate to the exchange circumstances, and I think that's really what we're trying to get at. What is the default, and I'm still not sure I get sort of the full breath of options. So when these factors are present, the default may be, as I think Gayle is suggesting, that I have to affirmatively choose to allow you to exchange my data. But what else are my options? I think it's hard for me to sort of follow a debate without understanding, then there's the opposite of that, right, which is, I'm in unless I tell you otherwise. Do we have any other alternatives? Just checking.

**Deven McGraw - Center for Democracy & Technology – Director**

I'm trying to think back to the paper that ONC commissioned on choice that we all got a copy of, but since it was 96 pages, maybe some of us haven't read it.

**Christine Bechtel - National Partnership for Women & Families – VP**

Right.

**Deven McGraw - Center for Democracy & Technology – Director**

Which would be understandable.

**Christine Bechtel - National Partnership for Women & Families – VP**

I read the 96,000 e-mails first.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes, so there may be some variations on how that gets applied, and I think even in an opt in or opt out scenario, there's some variation on when that choice gets applied. Say you've got a central database model where there's data aggregation, which triggers one of the factors. Is the choice about whether your data is in the database to begin with, or is it a choice about whether anybody can ever get it out?

**Christine Bechtel - National Partnership for Women & Families – VP**

Right.

**Deven McGraw - Center for Democracy & Technology – Director**

States are making, are having lots of different permutations about this, so I suspect there's probably a lot of different ways to slice and dice it. But, to me, the most important part of this conversation is sort of what are the factors that trigger consent beyond what the law requires.

By the way, we're not trying to rewrite law here. There are some laws that are in here on the books that require a consent in certain circumstances, and we're not going around that. But thinking about the new arrangements that are being created out there, to what extent are they deviations from the norm that patients are used to such that allowing patients to have some choice about whether their data is part of it is part of fair information practices.

Again, remember that individual choice and participation is in fact one of the fair information practices, and this articulation here was thinking about the circumstances under which we want to be very clear that some choice ought to apply.

**Christine Bechtel - National Partnership for Women & Families – VP**

I'll just close by saying I think that the factors are very well thought out. The meaningful choice elements are very well thought out. I really support them. I have a quick question about the factors, which is the fourth factor around data aggregation from a source outside the provider's record. I just want to make sure that would not include patient supplied data, which would be outside the provider's record like from a PHR or tele-monitoring, things like that.

**Deven McGraw - Center for Democracy & Technology – Director**

One could argue that consent is already there.

**Christine Bechtel - National Partnership for Women & Families – VP**

Right.

**Paul Eggerman – eScription – CEO**

... patient ....

**Deven McGraw - Center for Democracy & Technology – Director**

But that wasn't what we intended.

**Christine Bechtel - National Partnership for Women & Families – VP**

Okay.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Adam?

**Adam Clark – Lance Armstrong Foundation – Director for Health Policy**

Actually, I had one follow up, actually just on that point is one that was going to be later questioned, but what happens when it is the patient who ... if we're thinking three, four, five years down the road and being able to extract that information? Is that something that is then an assumed consent wherever that information goes?

**Deven McGraw - Center for Democracy & Technology – Director**

We addressed this question in the context of exchange between providers. I think we do have on our

long-term calendar getting to the individual access and individual rights to data. We didn't mean to suggest that that wouldn't require consent. I suspect we'll get there. But we haven't yet.

**Adam Clark – Lance Armstrong Foundation – Director for Health Policy**

If you look at the PatientsLikeMe approach, right now it's just patients self-reporting, but it's easy to see down the road that you're going to be able to get clinically annotated information from your record and distribute it however that individual sees fit. But I'll go back to an earlier point where, and this was just one of the questions that you had, the number one regarding limited to the individual who is the subjects of the patient. I know, I'm sure you're thinking about this, but just really wanted to stress the role of caregivers in this, particularly when, if you are going through chemotherapy, the stories that I heard, you are not able to take care of yourself.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes. No, no, no.

**Adam Clark – Lance Armstrong Foundation – Director for Health Policy**

A caregiver will need to be able to have certain kinds of information.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes. We didn't intent to say that caregivers couldn't get access to data. What we were specifically looking at there is whether, again, the definition of treatment under the HIPAA privacy rule isn't means that a physician could take a look at your data in order to treat another person. And so I think what we were saying is, in those answers is that in most circumstances to have your data use to treat somebody else ought to, they ought to get your consent, and we had a sort of placeholder for the maternal fetal context where, because sort of needed to explore that there might need to be some exception to that. But in general, we thought that isn't answered. Your data shouldn't be accessed to treat somebody else unless you've given permission to do so. Presumably, in a family member's situation, you would probably ordinarily give that permission unless you have a specific reason not to.

**Adam Clark – Lance Armstrong Foundation – Director for Health Policy**

I just raise something about it, and then I'd finish just with this, but when you'd mentioned we're reviewing consent from the standpoint of a patient's participation in exchange, are you talking with patients? I know we all mean very well here, and we're all trying to think from the vantage point of the patient, but is there an intention to have focus groups or has ONC looked at this? I think really flushing out how people are going to view this issue is going to be important.

**Deven McGraw - Center for Democracy & Technology – Director**

I don't know if they're planning any focus groups. We have, you know, Christine is a member of our tiger team. We had to keep it small in order to try to make progress. I think we ultimately hope that the public is paying attention and will give us some feedback on these in the same way we hope you all will give us some feedback on this.

**Christine Bechtel - National Partnership for Women & Families – VP**

... has in fact done some focus groups on this. There is a body of work on this that does exist, and then that is part of what ONC is building, as I understand it, in terms of the consumer education campaign, so you're right to ask the question, and we should get more information. Excellent.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Marc, Judy, Gayle, Neil.

**Marc Probst – Intermountain Healthcare – CIO**

By the way, Paul, we can do our presentation really fast, so we're okay. You guys have done a terrific job in what I think is an amazingly difficult position, but just a few thoughts that I've gone through, and I'll have to tell you. My bias walking into this conversation was more in line with the outspoken paper that was done that Judy talked about. I think we're dealing with a very sensitive issue. Neil, you talked about kind of the apathy for opting out. I think there's also an apathy for opting in, so if everyone has immediately opted in, that isn't going to immediately trigger people to say, I'm going to go opt out of this thing because I don't want it. And so part of the problem I see, and this is unique to the state I'm in, we're going through this very debate. We probably have half the population opted in if we had just started when we started the debate versus have it go on and on. I mean, really, it has put a big delay in it.

Break the glass, that part of the conversation, to me, that's opted in. If someone can access that by breaking the glass, that doesn't stop someone in an affairous way to breaking that glass and getting information. And once it's out, it's out. And so that concerns me a lot just on the whole break the glass component.

A lot of it comes down to accountability. As a provider organization, we have accepted accountability for individual's information, and I think part of the discussion needs to be, either at a federal or state level, who is going to take that liability? If you're telling us we must opt everyone in, which would be opt out, which is so confusing until you go through this thing, but if you're going to do it that way, are we still, as a provider organization now I'm speaking, liable for that information if a breach in privacy occurs?

Right now we feel like we absolutely are, and so it puts us in a situation that's pretty difficult. If Latanya Sweeney were here, and maybe she's on the phone, she'd tell us there are technologies that we ought to be looking at that might help us solve some of this problem and allow people to opt in more easily into the process. I think those were the biggest things I had there. Again, I think you've done a terrific job and it certainly opened my eyes to some things, and I just had those specific issues.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Judy?

**Judy Faulkner – Epic Systems – Founder**

One of the things on that list right there that I think is of great concern is the one about sensitive data because so many records have sensitive data in them: reproductive data or mental health data or whatever. And so that's going to be a large number of records, so really if that's there, then that counteracts against the directed exchange because it's going to be in an awful lot of records. That's one of my concerns.

Here are some of the statistics that I gathered. I looked at organizations who cover 13 million patients, and 60,000 records were exchanged in interoperability. With those who did opt in, they served almost 6,000 records, about 14,000 were exchanged, and one percent refused. That is with the record will go over with all data, including sensitive data.

With opt out, it's interesting. They had 3.5 million patients and 45,000 records exchanged, so there's a question in my mind. Is there some reason for that? It's a much higher percent. Is it that because opt out, opt in has an extra burden of work, and they're not doing it, and is that why you have such a lower percentage with opt in than you do with opt out? I don't know the reason. I'm just hypothesizing, but we have those numbers there.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

What data is this you're citing from?

**Judy Faulkner – Epic Systems – Founder**

This is from just looking at different customers.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Your Epic customers?

**Judy Faulkner – Epic Systems – Founder**

Yes. Right. So we're looking at their data to see that what we found, as I said, was, well, we did have a group of customers who were opting in found it too burdensome and switched to opt out.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

I assume you have consent of your customers to be ....

**Judy Faulkner – Epic Systems – Founder**

We leave it up to them. We do not touch which way they do it. We just supply the tools. We have really basic – the range of those who refuse to have the data sent varied between one percent and 4.5%. In other words, those who said send the data, even though it includes all information, was between 95.5% and 98.7%, actually ....

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Gayle?

**Gayle Harrell – Florida – Former State Legislator**

Yes. One of the points I do want to make very, very, very strongly is that patient education is such an important component of this, and I think that we, on the national level at ONC has a real responsibility here and that we need to have, there really needs to be a component of what ONC is doing to create the public awareness and to inform patients what meaningful choice really is, and I hope that part of our framework and where we're going in our vision for really creating the kind of interchange that we all view necessary is a part of that education component, and that the ultimate responsibility, of course, as ... falls with a record holder to be responsible for that record and what happens to it. However, there are lots of areas where the education component can be done in a very general, broad way for the public. And I hope that the ONC will use the bully pulpit that they have to really create that and use some of the resources that are given to the ONC to make sure that this is a critical component.

We all want to have meaningful exchange of records, but the ultimate person who is at risk and not everybody plays by the rules. Believe me, there are lots of bad folks out there. Not everybody. And we assume you play by the rules, but I have to tell you there are lots of folks who don't. And we need to make sure that personal, that privacy is the ultimate concept and value that we have to make sure the structure we put in place really recognizes that privacy component. But the responsibility for the education needs to be a little bit broader than just the individual provider and that the tools are there through the ONC to do that.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Neil?

**Neil Calman - Institute for Family Health - President & Cofounder**

New York State this year has been dealing with an opt in, opt out debate around organ donation. I think California has too actually, as the first two states to basically say since the majority of people in the state

favor organ donation, why not make organ donation the default and have people on notice that starting on a particular date, if they're involved in a motor vehicle accident, etc., that their organs would be up for donation unless they opted out of the process, a way to save lots of lives, and to make organs that are now largely in short supply available, have great impact on public health. So I think this discussion is taking place in a number of venues.

I just want to say one more thing about sort of the opt in, opt out thing. I think I hear what you're saying, Gayle, about sort of our constitutional rights and stuff. Part of what happens, I think, when you tell the country we're doing this thing, but you have a right to participate, is you're also saying, we don't really trust what we're telling you about our ability to keep your information private and secure. If that's the only reason, if we could guarantee people that we could keep their information private and secure, we wouldn't be having this discussion.

It's only because we don't trust that, right? That we're basically saying to people, well, you can opt in or opt out of this stuff because we're not sure that we can really create mechanisms that keep that information like that, and I think that that's part of the concern of doing it is that we're basically saying to the public, you know, this is something scary. I mean, that's the underlying piece of this. It's got some benefit, but it's also got some scary stuff about it, and you should really think twice about whether or not your information should be made available.

I would just make the point that I think we're just dealing with this in a point in time, just like other things. Ten years from now, we might not even believe we're having this discussion because it's going to be so much the standard of care that information is exchanged electronically through all kinds of mechanisms, and I think the rules that you guys have put in place for the appropriate use of data or the rules you're proposing are really the answers. We just have to be able to have very, very strict guidelines that basically say how data can be used, how it can be stored, how long it can be maintained, about third party use, and other things. Once we do that and we make those things as rigorous as we possible can, then I feel secure in basically saying to people, I suggest that that be the default situation is that data is exchanged that way. I think we should focus more on sort of the rules and how data is used and really start to have that conversation, and I really support the way that that stuff was outlined there because if we can do that, then I don't really personally have the same concerns about the privacy and security of the information because it's being supported as strongly as possible by the rules we have about the data use and exchange.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

So I just want ....

**Gayle Harrell – Florida – Former State Legislator**

May I respond to that?

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Okay.

**Gayle Harrell – Florida – Former State Legislator**

I have a daughter who spent four years in the air force. I have a son-in-law who is in the air force currently, and we've had electronic health records in the military and in Veterans Administration for many years. So far, between the two of them, they have ten breach notifications. You know, that their health information was on a laptop, their ID numbers or whatever. Between the two of them, they have a file like this on breach notifications.

I think the public is very concerned about that. You read, you know, Virginia had ten million records or whatever recently divulged or lost or stolen, I guess they were. And there's a great concern of the public out there on what happens to their individual health information. And they're very concerned that there are bad players out there. There's no doubt about it. There are bad players out there.

When the level of confidence in privacy and security has raised to the level where we don't need to have these conversations, then perhaps opt out is the correct default. But when there is that public concern, where there is not the proof in the pudding, and you don't have the mechanisms in place or at least there's not the confidence of the public that the mechanisms are in place, I think the only true choice that really gives the patient control of what happens to the very personal and private information is the opt in one. And I think we're a long way from having that confidence in the system.

We all want at this table for electronic health records to succeed. We all want to have the exchange, and I think, as the public sees things evolve and gain some confidence in the ability to do that, perhaps at a later time, the opt out might become the default. But right now, if you want people to have confidence, you have to give them the choice.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

We're going to bring it to close, but Joy and then I have one comment.

**Joy Pritts – ONC – Chief Privacy Officer**

I'd like to respond to what Neil and Gayle have both said. I think that when people have more confidence in the privacy and security of the information that it will definitely improve people's attitudes towards having their health information shared. Having said that, I've been in this field for a long time, and I have been involved in focus groups and lots of public debate on this topic. I believe that there is a core group of individuals that it's not the privacy and security that is driving their concerns. It is more really from a philosophical concept of autonomy. They feel like they are human beings, that they should be respected, and they should be asked, and they don't necessarily – that doesn't mean they're going to say no, that they don't want their information shared, but that they want what I refer to as the common respect of at least having the choice.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

I just wanted to also congratulate the group. I think this is actually the bullets with the triggers, I think it's a wonderful articulation and summary and distillation of the issues and essentially what you called the triggers. I think that's a really nice way, a really nice framework of presenting it. The other piece is, we've recently replayed the passion. That doesn't mean – well, it indicates there's no lack of caring, and I view it just as sharing the love.

**Deven McGraw - Center for Democracy & Technology – Director**

That's what our calls are all about, Paul.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

That's right.

**Deven McGraw - Center for Democracy & Technology – Director**

Just big love fest.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

That's right. I'll add one thing that the group may want to think about, and it was stimulated by Judy's reading of her experience in one vendor's exchange group. And she talked about opt in and opt out and

how she had a heterogeneous group of users who choose one or the other. And the thought occurs, do we think that the patients had the same understanding of what they were or were not doing across those groups? If not, then what do we think the heterogeneity has done to the underlying privacy or the trust?

I'm not sure I asked it right, but the question I'm asking then is should you be asking whether uniformity actually is something we ought to give guidance on in terms of opt in and opt out? Do people understand? If everyone were given the choice of opt out, or everyone were given the choice of opt in, and they were educated on it, would they be closer to understanding what was happening to their data than if we had some states or communities having opt in or opt out policies? Was I any clearer? It didn't look like it.

**Paul Eggerman – eScription – CEO**

I'll let you answer that question ....

**Deven McGraw - Center for Democracy & Technology – Director**

That was actually, it's interesting that you said that, Paul, because what was running through my mind when Judy was giving her statistics is I don't have enough information to be able to judge those models because it's just the outcome. It tells me nothing about how that choice was implemented, how much time people had, when they were offered it, how much education did the community give? How much education did the providers give?

**Judy Faulkner – Epic Systems – Founder**

... all of that.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes, and so, for example, if you look at ONC's paper, what's illuminating about it is not so much that some chose opt in and some chose opt out, but really comparing the differences and approaches in terms of there are opt in that states have chosen with, in my view, lousy level of patient education, and there are some other places where it's opt out that they did a whole lot more on the front end to give people. And so in my own just personal opinion, if I were to judge those two, the far more important goals were met by the educational process and the transparency and giving people sufficient time.

Having said that, I appreciate where Gayle is coming from with respect to what the default is for folks who just notwithstanding all the education because we said, as a team, that all of that should apply regardless of what the default mechanism is. I can understand why they feel that way. I think ultimately we may not, even as a policy committee, be able to reach consensus on that aspect of it. But more importantly, be able to endorse the concept of choice in certain circumstances as a requirement and that the choice has to fulfill certain elements, and then, from there, there just may be some judgment calls that the agency just might have to make, given all of the rich discussion that we've had about this.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Let me try one more time to phrase my question in an understandable way. I'll apply your principles.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes, maybe Paul will get it this time.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

That's right. So maybe I'll apply principle two, which is what would the patient expect and would the patient be surprised. In, let's say, two of Judy's customers, if the patient of a customer had lived under one rule, whether it's opt in or opt out or a different educational effort, and their information got sent to

another customer with a different either opt in or opt out and different education, would they be surprised by what happens in that other customer's EHR?

**Paul Eggerman – eScription – CEO**

That's hard for me to predict. From what I know of the systems involved, it's really directed exchange anyway, and so the situation that Judy is describing, we're saying that no consent is needed.

**Judy Faulkner – Epic Systems – Founder**

Well, it's ... a lot of the records may be containing sensitive data.

**Paul Eggerman – eScription – CEO**

May, except for the sensitive data.

**Judy Faulkner – Epic Systems – Founder**

It could be a lot, yes.

**Paul Eggerman – eScription – CEO**

Except for the sensitive data. That's correct ....

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

I guess what I'm ping back is another question to add to your list of questions whether there should be uniformity on the policy. Should ONC be recommending that the country have one uniform either opt in or opt out?

**Paul Eggerman – eScription – CEO**

No, because in some sense the people who advocated the first alternative are saying that there does not need to be one policy.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes. We already answered that question.

**Paul Eggerman – eScription – CEO**

We actually already answered that question. In some sense, if we go back to the statistics Judy responded, in effect, different customers make different assessments of which was the right way to go about things. And so that's, in other words, Judy is sort of like an advocate for the first alternative because that sort of says well that's a reasonable thing to do. They sort of knew their patients. They knew their circumstances. They knew what would surprise them and wouldn't surprise them, and they made their own determinations, and so that's the argument for alternative number one.

In looking at these, I just want to make the observation our tiger team did not make a decision on this either. You can sort of see why. This is a very rich discussion. On the flip side, we've got to understand what ONC needs us to do. As our advisory council, we do our best work when we deal with something that is difficult and controversial, and this is difficult and controversial.

**Deven McGraw - Center for Democracy & Technology – Director**

Right, but I actually think—

**Neil Calman - Institute for Family Health - President & Cofounder**

Given the answer—

**Deven McGraw - Center for Democracy & Technology – Director**

Sorry, Neil. Go ahead.

**Neil Calman - Institute for Family Health - President & Cofounder**

I was just going to say, you've sort of given the answer. In a sense, we're all sort of talking around it. The real answer to this is about the education, right? And then it really – and what we should require is that educational process. And we should not only require, but specify it. Then we've got to figure out how it's going to be delivered, in some places, either public education, in some places through providers, whatever. That's really the key, the homework of this is really the education.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes.

**Neil Calman - Institute for Family Health - President & Cofounder**

Then the education is provided, the individual providers might have different options of how they want to deal with the actual consent stuff. I think not prescribing that is probably the best you're going to get as a first option, which is probably why you put it up that way. We needn't put opt in versus opt out. You put in provider choice versus opt in.

**Paul Eggerman – eScription – CEO**

Right, well ....

**Deven McGraw - Center for Democracy & Technology – Director**

Well, that's because the fundamental, we had a recommendation that said there shall be choice.

**Paul Eggerman – eScription – CEO**

Right ....

**Deven McGraw - Center for Democracy & Technology – Director**

When these factors are present.

**Paul Eggerman – eScription – CEO**

Yes, but that's also ... when the tiger team came out, some people said let individual providers decide. Others said opt in. That was....

**Neil Calman - Institute for Family Health - President & Cofounder**

What they can't decide upon is the fact to make sure that their patients are educated about what's happening to the information.

**Paul Eggerman – eScription – CEO**

That's correct. Excellent point.

**Deven McGraw - Center for Democracy & Technology – Director**

That's right.

**Paul Eggerman – eScription – CEO**

It is one of the criteria, but excellent point. It is one of the criteria, but an excellent point.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

What you have requested is whether this committee, with the input you receive, can accept where you are now and move forward. Let me try that one. They've presented a series of recommendations. The final recommendation was really just offering up the two kinds of choices without a decision, but at the state, so they have made some recommendations like the triggers, what a meaningful choice is, and can we accept all of their recommendations so that they can take that as accepted and move on? As they explained, in the end, in two months, they'll come back with a package and say, look, this is now for the approval, go/no go approval. That's a different choice. Right now they need to have an adoption of where they are so they can move on with this as a base.

**Deven McGraw - Center for Democracy & Technology – Director**

In other words, maybe I could say accepted. You're heading in the right direction. Keep going and refining.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Right. Any further discussion?

**Judy Faulkner – Epic Systems – Founder**

I don't know what we're saying on this recommendation on what factors trigger the need by provider to obtain the patient's consent on that list?

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

We're saying that that's a good list.

**Judy Faulkner – Epic Systems – Founder**

What are we saying happens to that list? Is it true that it will require consent, or is it not true?

**Deven McGraw - Center for Democracy & Technology – Director**

We identified those in tiger team discussions as being factors that would trigger the need for patient consent. We acknowledge that on your sensitive data issue that we are doing some more work on that aspect of it because it was tripping into the more granularity that we wanted to try to get to in the next phase of discussions. It doesn't mean that we wouldn't, as we wrap them all together, think about how those factors interact with others that sort of surface themselves in subsequent discussions.

But that we— So in other words, we've identified and, quite frankly, there wasn't a huge amount of pushback on the call about those factors, Judy, beyond the ones that you've articulated. So it's not like we don't know that there's some more work we need to do to make those more clear – Neil's question on the first one. But, in general, we're heading in the right direction by, number one, identifying specific factors that deviate from the traditional patient provider relationship and that choice should be applied when those factors ....

**Judy Faulkner – Epic Systems – Founder**

If we agree to this, we're not agreeing, therefore, that what the top says? We're agreeing, but it doesn't hold?

**Deven McGraw - Center for Democracy & Technology – Director**

No, I wouldn't say that, Judy.

**Judy Faulkner – Epic Systems – Founder**

Then I don't understand.

**Deven McGraw - Center for Democracy & Technology – Director**

I think what this committee is being asked is are we, with the set of factors that we have begun to articulate here, are we heading in the right direction in terms of where we want to tell ONC they ought to apply different levels of choice with the knowledge that we're not going to back and rehash all of this, but we could be continuing to refine those to make them more clear given that, again, we're working on a very tight timeframe here, and we acknowledge that there may be some circumstances that haven't fully thought of that require us to articulate with some more specificity some of the factors that we've identified here, but I do think we are saying, this is our first attempt to come up with these factors, and we want to get your feedback on it, and we want to get your feedback on it, and we want you to tell us keep going.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Are we ready to vote? All those in favor of accepting the recommendations of their group?

**W**

Aye.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Aye.

**M**

Aye.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

... comment is an ... process, an intake process. All those opposed?

**Judy Faulkner – Epic Systems – Founder**

Maybe, Paul. I don't know what fine-tuning means versus getting rid of it. Can we get rid of it if we fine-tune it?

**Deven McGraw - Center for Democracy & Technology – Director**

It's entirely possible that we could.

**Judy Faulkner – Epic Systems – Founder**

I'll consent then on the condition that we could still possibly get rid of it.

**Deven McGraw - Center for Democracy & Technology – Director**

By consensus of the tiger team.

**Gayle Harrell – Florida – Former State Legislator**

Yes. And I just want to verify that there is no decision on opt in, opt out, or whatever.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Correct. There wasn't on the slide, so....

**Gayle Harrell – Florida – Former State Legislator**

Correct. Okay. Just want to make sure.

**Paul Eggerman – eScription – CEO**

You're accepting ... current ambivalence.

**Gayle Harrell – Florida – Former State Legislator**

Ambivalence.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

So we have two more yes votes, is that true?

**Gayle Harrell – Florida – Former State Legislator**

Yes.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Okay. So we have a unanimous vote then.

**Art Davidson - Public Health Informatics at Denver Public Health – Director**

Paul, this is yes too. This is Art.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Thank you, Art. Anybody else on the phone? Great. Thank you very much. By definition, this is a privacy topic, so it goes over time. Thanks again. It was really yeomen's work.

**Paul Egerman – eScription – CEO**

Our pleasure.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Remember, you said that with love. You did promise me, Paul, that the next topic would be shorter than scheduled time, so it is.

**Paul Egerman – eScription – CEO**

Let me just say good afternoon. I'm Paul Egerman. I'm here with the adoption certification workgroup, and we wanted to very quickly tell you a little bit about what the adoption certification workgroup is doing, our recent activities, and our areas of focus. I would say, even though we're going to spend a very brief amount of time on this, but to remind everybody, certification legislation is sort of like ... meaningful use.

This is a very powerful, public policy lever that ONC has, and so this is something that is extremely important. All the activity and the interest has been on the meaningful use side. I don't want to say all of it, but like 98% of what you read about is on the meaningful use side, but this is also something that is extremely important. We have made some very significant changes in the certification process.

These are the members of our workgroup team, and these group people have continued to work and be focused on this issue. We've commented on the NPRMs, and we are continuing to meet and review certification. Even though we've made good progress on it, we don't necessarily think that on our first shot that we necessarily got it 100% right. A quick list of some of the recent activities, continued focus on certification, discussions with some of the ONC staff, and we're going to have, and we've prioritized some areas of focus, and we're going to have a hearing soon to talk about barriers to EHR adoption, as we sort of focus more on the adoption piece, and Marc is going to talk a little bit about that.

**Marc Probst – Intermountain Healthcare – CIO**

Great. We've had tiger teams and cheetah teams, and based on the content of today, I think we're going for panda team. We're going to go through this quickly and where we're at today. Also, any of you that would like to opt out, you can just get on your laptop or something, as we won't force it.

We've had some good presentations. We've really been – certification was such a focus for this group for a long time, and we're really proud to see where certification has got to and the work that ONC has done on that, and so we appreciate it. Obviously we've been paying attention to meaningful use. But we really kind of did have a pause, and we took a step back and said how could we really support the ONC team more in the area now of adoption because we think that's probably turning into a pretty hot and important topic. So we started out.

Judy has set up several good meetings for us, but we've talked with Melinda Booton and Ned Ellington. Melinda really focused on a lot of the modeling, the analysis, what's happening or what will happen, and gathering statistics, and then Ned on the overall provider adoption areas. For Melinda, a lot of the data collection, so we put a list of things together as a workgroup and said these are things we think we could be helpful with. What came back was a lot of these things are actually already happening, and let's not do redundant work.

Around data analysis and collection, I think Melinda has got some terrific activities going on, physician surveys around adoption. What can they do in monthly updates from CMS on what they're doing? So they're gathering some good statistics. They're also putting a model together on adoption and, later this summer, they're going to have a conference on it, have invited our workgroup. I'm sure the other members of the policy committee would be welcome to air in on that, but they would really like some expert input on the modeling, what it looks like relative to adoption.

Supporting and encouraging adoption, a lot of focus on the smaller providers, smaller hospitals, rural hospitals, and some of the needs that they have, and then ONC performance measurement where her team actually goes back to Congress and reports on the status of meaningful use, and are we really achieving what was meant to be achieved? Then Ned on the whole provider adoption side just looking at the RECs, I think a lot of work is going right into the regional extension centers. Are they being successful, and is there work being done that can be shared across the organizations?

We were just getting a feel for what was going on, and we really appreciate that input from ONC. That led us to just asking what specifically could we do. Certainly participating in this panel at the end of the summer to provide some ideas, individual discussion, so if they have specific questions around providers, they can get a hold of me, or if the payers, they could get a hold of Charles, and just making ourselves available that way. And then trying to aggregate, they only have so much bandwidth to talk to vendors and other people, and Paul has been really terrific, frankly, in getting out and talking to some of these organizations and just providing that feedback to ONC.

We had a phone call where we went through and talked specifically about some areas, some of the adoption challenges. I really liked the term thoughtful non-adopters. We were using naysayers. But we really think these are people that have thought about it and just said, you know, it's very expensive. When they look at the return on it, they're probably not as interested. How do we engage that group of people because the incentives are out there, but it's a far off greater cause that we're trying to do than just simply the incentive dollars that are out there?

Another area that ONC thought we might be able to focus on is coordinating with the implementation workgroup. Frankly, we haven't gotten a lot of momentum around that or a discussion around it. Then, finally, monitoring the certification process, whether it's been effective, and so that's another area where we specifically think we can provide help.

Then this list, we won't go through all of them, but this is a list of additional areas that, as a workgroup, we've talked about potentially being of use to ONC and the teams that they have in place and providing

information to those teams. Let me get to the meat. We talked about a hearing and really looking at the areas of adoption. We think that's pretty important at this point. Are the concepts being adopted, and what kind of successes can we see?

We talked about setting up a hearing. We're working with ONC to do that relative to adoption and the barriers around adoption. We think there should be a separate session for physicians and hospitals, but the issues are unique to those two areas, so that might be a day each. We'd rather focus on the small and medium sized end users, as Melinda and Ned had talked about because their issues are kind of specific, and because I think we're hearing a lot from the Intermountain and the partners and the people that maybe are more adopted into using EHRs and would like to learn what some of the issues are of those that aren't so fully vested. Obviously have vendors and practitioners both involved, and then really looking at the barriers and not just to identify the barriers, but what kind of lessons have been learned and what can we do going forward, and so our goal is to provide that list to ONC.

Our next steps, we want to support the conference that Melinda is holding. I don't think we have a date yet for that. We'll be having a follow up call with the workgroup to prioritize some of those other issues that we outlined, and we're going to work on specifically setting up this hearing for probably early this fall based on barriers to adoption and some of the recommendations. That's where we are right now, the panda team. Any questions?

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Questions, comments?

**Paul Eggerman – eScription – CEO**

Good job.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Gayle.

**Marc Probst – Intermountain Healthcare – CIO**

Did we catch up?

**Gayle Harrell – Florida – Former State Legislator**

First, I'm going to have to leave in a minute because I have to catch an early plane, unfortunately. But I do want to say that I think adoption – addressing the issues, especially of our smaller hospital and those small practice groups, you know, two, three, four physicians is really going to be critical, and I'm so pleased that you're going to be doing some hearings and dividing them up because the issues are very, very different. What I hear from the physician side is they're very confused out there, very confused.

I think the RECs are in a place. As soon as the RECs are up and running and really getting out there, of course, it's still very, very early for them. The quicker they are up and running and really informing the physicians about it, the quicker this will happen and the confusion I'm hearing, and thank goodness the rule is out now and people know exactly what is going to be expected and required. I think that's going to make a big difference. But it's a critical thing that you're doing in looking at what is happening and addressing why. I think the issue why you have those reluctant adopters. Why they are postponing, and the analysis really needs to target the why. The who and the why, and then bring back to us some recommendations as to how to address that.

**Marc Probst – Intermountain Healthcare – CIO**

I think that's right on, Gayle, and our workgroup, I mean, that really, as we drove toward the smaller practices and the smaller facilities. I want to make it pretty clear or very clear, ONC is doing a lot of work in these areas, so they are gathering statistics, as Judy was talking about, being fact based. I think we're going to get a lot more facts as time comes along, and it's just really encouraging to see the organization of ONC and the work that they're doing, and hopefully we can be supportive in these areas.

**Paul Eggerman – eScription – CEO**

And the thing I might add, I mean, first of all, I'd certainly agree with you, Gayle. We're looking at small physician groups and small hospitals, but we're looking at it not just from the standpoint of the provider, but sort of like the entire lifecycle of what's involved in acquiring these systems. The issue in terms of outreach, I spoke to the CEO of the vendor that sells to small to medium sized hospitals, and that individual told me that he currently has an 18-month backlog. In other words, if somebody signs a contract with him, he doesn't even get started working on them for another 18 months before they can begin implementation because he can't handle all the business that he's got, which is an interesting thing.

The question is, is that unique to that vendor, or is there something else going on in the industry that we need to know about? Some of the evaluation of what's going on, on the vendor side, may be somewhat difficult for ONC to do, but it's something that I think we can do from an outreach standpoint. But also, as we look at this, Marc talked about thoughtful, non-adopters, but we also want to look at small physician groups and small hospitals who want to adopt, but for some reason they can't. There are some barriers along the way that's stopping them. Either they've having trouble finding a vendor; they don't know where to start. They've got a vendor, but it's taking 18 months. We want to also try to identify the people who really want to do this but, for whatever reason, are finding obstacles in their path.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Any other comments, questions? Thank you very much for the update. We look forward to your reports. Our final group is an update from the information exchange workgroup, and I think Micky is on the phone. Great. Thanks.

**Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO**

Yes, I'm here.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Go ahead. We have your first slide up.

**Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO**

Great. I believe there's just one other slide after this, so this is Micky Tripathi.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

You're 50% done.

**Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO**

Yes. Exactly. This is Micky Tripathi. Good afternoon, everyone. Sorry I can't be there in person. I just wanted to give you actually just a very quick update on the information exchange workgroup. I think it shouldn't take more than a half-hour or so. All of you have time, I'm sure. We've had some changes in the workgroup, which are really reshaping it toward what we see as being the future agenda, and I described that at the last HIT Policy Committee meeting, so I just wanted to report on where we are with respect to reconstituting and reshaping the workgroup for the work ahead.

The first thing I'd like to report is actually sort of it's very good news and very bad news and very good news with respect to the leadership of the workgroup. The very bad news is that Deven McGraw has pleaded for mercy and has asked not to be cochair of the workgroup, but continue to be a member of the workgroup in light of the other workgroups that she is co-chairing, and so first off just wanted to recognize Deven and thank her for all the terrific leadership she's shown on this, and I know that she continues to show with respect to other activities here, but I've really, really enjoyed working with her as the cochair of this workgroup and want to thank her for that.

The very good news is that David Lansky has agreed to be the cochair of the workgroup, so David is out of the country right now. He'll be back next week, but I'm very much looking forward to working with him, and I think he'll offer tremendous leadership to the workgroup.

We've embarked on supplementing the workgroup membership in two areas that we think are very important to the future work of the workgroup, and that's mainly in the area of Medicaid and public health, so the focus of the workgroup is going to be two-fold. One is specific transactions related to meaningful use, so it's really essentially, as someone from ONC put it, holding a mirror up to the market and saying what are the things that are going on in the market that we need some policy work to help facilitate them and make them a little bit easier going forward. One is related, you know, the specific transactions related to meaningful use, and the second is issues that will emerge from state level implementations, and you can imagine those issues being sort of within state issues, as each of the states embarks on the HIE work that they're doing under the 3013 funding that they're getting, cross-state issues, as well as the intersection with the Nationwide Health Information Network, as that starts to unfold.

We see the workgroup as being focused on those two levels. One is the specific transactions related to meaningful use and how can we make those better on the ground. And then, second, the emerging issues that will come up from the state level implementation work as it starts to unfold. But the agenda going forward, I would put forward the caveat that because my cochair, David Lansky, is out of the country, and we haven't yet had our first meeting with the newly constituted workgroup, these are just sort of high level thoughts about what we're going to be doing, but obviously we'll come back to you once we've been able to dive down more deeply into it.

I think it's really sort of two things first and foremost. One is about the next level investigation into labs and e-prescribing, which we had done in the first round last year, but now that the final rule is out, now taking a look at those areas again, seeing what might be a part of a second phase investigation of those as they've sort of taken on greater importance with ONC, program information notice that went out to all of the HIE activities across the country, and seeing what further issues there might be there that, from a policy perspective, can be resolved.

Then, second, looking at summary care exchange, which has been moved to the menu set, I think, as all of you know from a meaningful use perspective, but it's still a priority area in the ONC PIN, and obviously is going to be very important in stage two and onward, so to the extent that there is a lot of variation in the market with respect to how summary care exchange could be implemented and is being implemented with respect to within enterprises and hospital systems that are doing it and thinking about the sort of cross-enterprise issues related to summary care exchange, that seems like another area that is going to warrant a lot of attention. In particular, provider directories, as we think about those at a state level, regional level, and perhaps at a national level, I think of ongoing interest and is going to start to be at a place where the rubber hits the road, I think, in the months ahead as the states submit their plans to ONC at the end of August.

Administrative transactions were going to be the third one that we're going to focus on. Now that that has been moved out to stage two, that I think will move down in our priority list right now, but again just a caveat that we haven't met yet as a workgroup, so would want to take the feedback of the workgroup members into account before coming back to you with a firm agenda and a firm schedule.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Good. Thanks. Thank you very much, Micky. Any questions or comments? All right. Thanks, Micky. Now I think we'll turn over to public comments.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Anybody in the room who wishes to make a comment to the committee, please step forward to the microphone, and anybody on the telephone, if you want to just press star, one to be connected or, if you're on the Web, dial 1-877-705-6006, and we'll take our first comment here in the room from Robin Raiford.

**Robin Raiford – Eclipsys – Director of Government Initiatives**

Hello. Robin Raiford, and just for the purposes of this comment, I'm Joe Citizen with a chronic health issue ... implanted ... in my chest for ten years. I get scared to death every time I come to these meetings something will happen to me. Somebody won't have my records. I'd rather be alive than somebody kill me from not sharing my records.

Five years ago, I went to San Diego, my back went out on me. My father died ... the day after the tsunami in Southeast Asia, and they put me in the hospital, gave me a high dose of steroids, and ran up a \$0.5 million hospital bill over 6 weeks and sent me home on 47 medicines. I was on three when I went in, so I really got screwed up. And they decided I was crazy because I was bouncing off the wall on 60 milligrams a day of prednisone. I don't know anybody who won't bounce off the wall.

I had a history of adrenal insufficiency. I was scared to death. I was scared to death. So for the consumer, here's your opt in, opt out, and of something very simple. Share your data; maybe we won't kill you. Don't share your data; oops, we killed you, but your data was safe. And get that point across that you could die.

And I gave the little chart that Paul passed around to you. I made one chart of – I make the wall charts with all the dots. There's another one made, and you'll be happy to know, I maxed out Excel. It can only be 72 characters in the font and 255 characters wide, and the chart was bigger than that, so I maxed it out, so for stage two, somebody needs to call Bill Gates to make it bigger, so trying to work that out.

And then the other thought I had, as I looked at you from Livestrong, is that until we get it worked out, come up with a bracelet. If you want us to share the data, could Lance Armstrong come up with a bracelet that's universally accepted?

**Adam Clark – Lance Armstrong Foundation – Director for Health Policy**

We're doing the Iron Man next year, so we'll have something ready.

**Robin Raiford – Eclipsys – Director of Government Initiatives**

Okay, because now all I have is a bracelet, and I'm allowed to have 64 characters wrong, and I'm there, and the next one is, just don't touch me. You're going to kill me. I'm probably at my three minutes, so I'll quit, but maybe the thought of what you said about opt in, opt out, about organ donation. I don't know any of the one million people who have died since the ION study, my mom being one of them, I'm hoping I'm

not the next, that would say that that's okay their data was saved. They'd rather have their loved on, to the child that your husband lost. They're rather have their loved on.

Just don't forget the patient in all this. Yes, it's hard. Yes, we need to keep going. But don't keep it so safe that people keep dying. Thank you.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Robin is the one that supplied one, the bookmark PDF for all of these rules. But, two, she's working on this very helpful matrix. She already has a poster, but I said it's got to be letter size. Anyway, thanks for that, Robin.

**Allison Viola – AHIMA – Director of Federal Regulations**

Hello. Allison Viola from the American Health Information Management Association. In regards to the certification and adoption workgroup, as you plan to prepare your barriers to EHR adoption conference or session, I would encourage you, if possible, to try to look one step beyond just adoption and try to look at the actual implementation efforts after you've adopted, as people are moving toward achieving meaningful use and actually using the EHR, as it relates to workflow analysis, resources, workforce, those types of things. If you could take one step down, I think that would help fulfill the discussion. Thank you.

**Lorraine Fernandes – IBM – VP & Healthcare Industry Ambassador**

Thank you. Lorraine Fernandes from Initiate. A couple of comments: I happen to belong to AHIMA, so I can reinforce a couple of points that Allison made and add some real world to it. With all the clients I work throughout the U.S., it's very high enrollment, just like you talked about, Judy. Do you want your data shared? I think every one of them, it's like 92%, 94%, 98%, so the public, when educated, really does get it and says, yes, count me in.

One of the organizations I work with specifically says when they're talking with their patients, whether it's the registrar, the physician, whomever, they make it very simple. Mrs. Smith, would you like to have your information shared electronically with your other patients? That's the patient perspective that I think we need to be mindful of.

Point number two would be being a health information professional who, for the first 15 or 20 years of my career, actually ran health information departments. One of the things that bothers me in this discussion is that perhaps there's an assumption that in the old paper-based world, records were secure. Not quite true, as some of us unfortunately know.

Records that were very interesting perhaps never made it back to the health information department. Records that were filed were filed in the wrong places or, God forbid, they were faxed to the wrong place. They were faxed to the drycleaner or the service station across – you know, those real world things do happen today. So I think, in the discussion, we need to make sure people recognize it's not just a privacy and security risk today, or it's not a patient education risk today. It's we're going to have greater ability. We can improve individual and population health. But it's just upping the stakes a bit, maybe so to speak.

The third point would be to the enrollment workgroup, as someone who has worked with a lot of data organizations over the years. It's kind of interesting when you look at data as the value over the last decade of the social security number has decreased because of states not allowing capture, patients being reluctant to share it, or patients purposefully giving the wrong social security number. As the "value" of the SSN has decreased over the last decade or 15 years, the value of the phone number has increased dramatically because we can carry our cell phone numbers anywhere we go in the U.S.,

whether we move temporarily or permanently. So a very careful analysis of the data elements is going to be necessary for the enrollment workgroup, and I know they're off to a good start. Thank you.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Thank you, Lorraine. We have no comments on the phone, so, Dr. Tang.

**Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO**

Thank you, everyone, for the committee, for all the tigers, pandas, and cheetah teams. Great work. Very passionate and energetic discussion, so thanks again and see you next month.

## **Public Comment Received During the Meeting**

1. One area of granularity was identified for further review... i.e. specific types of more specific information... However it does not address granularity related to a "Provider"... i.e. can the patient consent to a specific individual or group or providers... i.e. only John Jones within "Moses medical Center" or only x department in "Moses medical Center" or only "Moses medical center" and not its subsidiaries or Moses medical center and All its subsidiaries... i.e. what is the Definition of a "Provider?"

2. Can you clarify what month the first incentive payments will be made?